Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

510(k) Summary for the ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown

SEP - 3 2008

Intended Use: The Kimberly-Clark* ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gown meets Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gown meets Level 4 of the AAMI Liquid Barrier classifications.

Device Description: The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are full-length, nonwoven SMS polypropylene gowns. They are constructed with raglan sleeves, hook-and-loop neck closures, and tie waist closures. The ULTRA Film-Reinforced Surgical Gown is film-reinforced for higher barrier protection. The ULTRA Surgical Gown fully meets the Association for the Advancement of Medical Instrumentation (AAMI) Level 3 requirements for liquid barrier performance. The ULTRA Film-Reinforced Surgical Gown fully meets the AAMI Level 4 requirements for liquid barrier performance.

Substantial Equivalence: The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are substantially equivalent to the predicate Kimberly-Clark KIMGUARD* and SPUNGUARD* Surgical Gowns in intended use, design, materials, and biocompatibility attributes. The performance attributes of the ULTRA gowns are substantially equivalent to the predicate gowns with the exception that the ULTRA Surgical Gown meets the requirements of AAMI Level 3 liquid barrier requirements and the ULTRA Film-Reinforced Surgical Gown meets the requirements of AAMI Level 4 liquid barrier requirements. The ULTRA gowns and their predicates are provided sterile and for single use.

Summary of Testing: The ULTRA Surgical Gown has been tested in compliance with the requirements of Level 3 liquid barrier performance requirements of ANSI/AAMI PB70: 2003 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities." The ULTRA Film-Reinforced Surgical Gown has been tested in compliance with the requirements of Level 4 liquid barrier performance requirements of ANSI/AAMI PB70: 2003. The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown also meet the requirements of the National Fire Protection Association (NFPA) Test Method 702-1980 for Class I. The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown have been tested in compliance with the biocompatibility requirements of ISO 10993 for surface devices with limited contact with breached or compromised surfaces.

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* Registered Trademark or Trademark of Kimberly-Clark Worldwide, Inc. or its affiliates.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2008

Mr. David M. Lee
Associate Director of Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K080795
Trade/Device Name: Ultra Surgical Gown
Ultra Film-Reinforced Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: August 15, 2008
Received: August 19, 2008

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

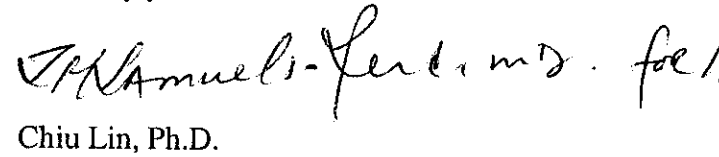
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Indications for Use

510(k) Number (if known): **K080795**

Device Name: ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns

Indications for Use:

The Kimberly-Clark* ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K080795

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Addendum:

The ULTRA Surgical Gowns AAMI Level 3 are available under the following Reference Numbers:

- 95101 ULTRA Surgical Gown, Small
- 95111 ULTRA Surgical Gown, Large
- 95121 ULTRA Surgical Gown, X-Large
- 95055 ULTRA Surgical Gown, Large (2 Pack)
- 95131 ULTRA Surgical Gown, XX-Large

The ULTRA Film-Reinforced Surgical Gowns AAMI Level 4 are available under the following Reference Numbers:

- 95411 ULTRA Film-Reinforced Surgical Gown, Large
- 95421 ULTRA Film-Reinforced Surgical Gown, X-Large
- 95431 ULTRA Film-Reinforced Surgical Gown, XX-Large
- 95511 ULTRA Film-Reinforced Specialty Surgical Gown, Large
- 95521 ULTRA Film-Reinforced Specialty Surgical Gown, X-Large
- 95531 ULTRA Film-Reinforced Specialty Surgical Gown, XX-Large

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2008

Mr. David M. Lee
Associate Director of Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K080795
Trade/Device Name: Ultra Surgical Gown
Ultra Film-Reinforced Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: August 15, 2008
Received: August 19, 2008

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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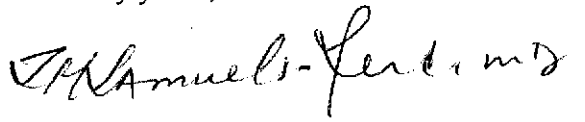
Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Indications for Use

510(k) Number (if known): **K080795**

Device Name: ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns

Indications for Use:

The Kimberly-Clark* ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080795

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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- 95511 ULTRA Film-Reinforced Specialty Surgical Gown, Large
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- 95531 ULTRA Film-Reinforced Specialty Surgical Gown, XX-Large

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 18, 2008

KIMBERLY-CLARK CORP.
1400 HOLCOMB BRIDGE RD.
BLDG 300, #1092
ROSWELL, GA 30076
ATTN: DAVID M. LEE

510(k) Number: K080795
Product: ULTRA SURGICAL GOWN & FLUID BARRIER SURGICAL GOWN

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 15, 2008

KIMBERLY-CLARK CORP.
1400 HOLCOMB BRIDGE RD.
BLDG 300, #1092
ROSWELL, GA 30076
ATTN: DAVID M. LEE

510(k) Number: K080795
Product: ULTRA SURGICAL GOWN & FLUID BARRIER SURGICAL GOWN

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 21, 2008

KIMBERLY-CLARK CORP.
1400 HOLCOMB BRIDGE RD.
BLDG 300, #1092
ROSWELL, GA 30076
ATTN: DAVID M. LEE

510(k) Number: K080795
Received: 20-MAR-2008
Product: ULTRA SURGICAL GOWN & FLUID BARRIER SURGICAL GOWN

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (http://prsinfo.clinicaltrials.gov). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

form may be found at the following link to the Federal Register Notice (http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm).

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Kimberly-Clark Request # 2015-9647; Released by CDRH on 03-28-2016

FDA CDRH DMC

MAR 20 2008

Received

March 17, 2008

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Abbreviated 510(k) Notification: Kimberly-Clark* ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown

To Whom It May Concern:

This Abbreviated 510(k) concerns the premarket notification for a product family of Kimberly-Clark* surgical gowns, labeled as either AAMI Liquid Barrier Level 3 for the ULTRA Surgical Gowns or AAMI Liquid Barrier Level 4 for the ULTRA Fluid Barrier Surgical Gowns. The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown are substantially equivalent to the predicate Kimberly-Clark KIMGUARD* and SPUNGUARD* Surgical Gowns in intended use, design, materials, biocompatibility attributes, and performance attributes. This Abbreviated 510(k) focuses primarily on conformity to a recognized consensus standard and on adherence to FDA's guidance on surgical gown premarket notification submissions.

Device type: Sterile surgical gown

510(k) Submitter: KIMBERLY-CLARK CORPORATION
1400 Holcomb Bridge Road
Roswell, GA 30076
Establishment Registration Number 1033422

Primary Contact for this 510(k) Submission:
David M. Lee
Associate Director of Regulatory Affairs
1400 Holcomb Bridge Road
Building 300, #1092
Roswell, GA 30076
Phone: 770 587 7167
FAX: 920 969 5160
David.Lee@kcc.com

* Registered Trademark or Trademark of Kimberly-Clark Worldwide, Inc. or its affiliates.

HHS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Requested by the FDA Request # 2015-9647; Released by CDRH on 03-28-2016

Confidentiality Request:	Pursuant to 21 CFR 807.95, please treat with confidentiality the information in this 510(k) and Kimberly-Clark's intent to market the medical devices described herein.
Recommended Classification Regulation:	21 CFR 878.4040
Device Class:	Class II
Panel:	General & Plastic Surgery
Product Code:	FYA

Please contact me if I can be of assistance.

Sincerely,

David M. Lee
Associate Director of Regulatory Affairs
Phone: 770 587 7167
FAX: 920 969 5160
David.Lee@kcc.com

AHB

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

-->

KIMBERLY CLARK CORP
1400 HOLCOMB BRIDGE ROAD
ROSWELL GA 30076-2199
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

390394230

2. CONTACT NAME

Lisa Peacock, SciMed, Inc., consultant submitting on behalf of Mark Bussone

2.1 E-MAIL ADDRESS

PEACOCKL@WINDSTREAM.NET

2.2 TELEPHONE NUMBER (include Area code)

706-216-3413

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

800-713-7754

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms

[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)

(b)(4) [redacted]

15-Nov-2006

Form FDA 3601 (08/2003)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form FDA 3514
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
3/17/2008	(b)(4) [redacted]	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☒ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Kimberly-Clark Corporation	Establishment Registration Number *(if known)* 1033422		
Division Name *(if applicable)*	Phone Number *(including area code)* (770) 587 7167		
Street Address 1400 Holcomb Bridge Road Building 300, #1092	FAX Number *(including area code)* (920) 969 5160		
City Roswell	State / Province GA	ZIP/Postal Code 30076-2199	Country USA
Contact Name David M. Lee			
Contact Title Associate Director of Regulatory Affairs	Contact E-mail Address David.Lee@kcc.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)* ( )		
Street Address	FAX Number *(including area code)* ( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Graphics: (301) 443-2454 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Sterilization
  - [ ] Packaging
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Response to FDA correspondence:

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Repose to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:
The purpose of this 510(k) is to allow Kimberly-Clark* to market the ULTRA Surgical Gown with an AAMI Level 3 Barrier Claim and the ULTRA Fluid Barrier Surgical Gown with an AAMI Level 4 Barrier Claim.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FYA	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K781682	1	KIMGUARD* Surgical Gowns and Drapes	1	Kimberly-Clark*
2	K842115	2	SPUNGUARD Surgical Gowns and Drapes	2	Kimberly-Clark*
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

surgical gown

	Trade or Proprietary or Model Name for This Device		Model Number
1	ULTRA Surgical Gown	1	not applicable
2	ULTRA Fluid Barrier Surgical Gown	2	not applicable
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K781682	2 K842115	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
FYA	878.4040	[ ] Class I [x] Class II
Classification Panel: General & Plastic Surgery		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

The Kimberly-Clark* ULTRA Surgical Gowns and ULTRA Fluid Barrier Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Fluid Barrier Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Note. Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)* ( )
Street Address	FAX Number *(including area code)* ( )
City	State / Province / ZIP/Postal Code / Country

Contact Name	Contact Title	Contact E-mail Address

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

ECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ANSI/AAMI PB70	AAMI/AAMI	Liquid barrier performance and classification of protective apparel and drapes intended for use in helath care facilities	PB70:2003	2003
2	ISO 10993-5	ISO	Biological Evaluation of Medical Devices- Part 5: Tests for in vitro cytotoxicity	5	1999
3	ISO 10993-10	ISO	Biological Evaluation of Medical Devices- Part 10: Tests for irritation and delayed-type hypersensitivity	10	2002
4	ANSI/AAMI/ ISO 11135-1	ANSI/AAMI/ ISO	Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical device	1	2007
5	ANSI/AAMI/ ISO 10993-7	ANSI/AAMI/ ISO	Biological evaluation of medical devices, Part 7: Ethylene oxide sterilization residuals	7, 1995 R 2001	2001
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Section 4. Table of Contents

Title	Section
Cover Letter	1
User Fee Cover Sheet	2
CDRH Cover Sheet	3
Table of Contents	4
Indications for Use Statement	5
510(k) Summary	6
Truthful and Accurate Statement	7
Class III Summary and Certification (This section does not apply.)	8
Financial Certification (This section does not apply.)	9
Use of Consensus Standards and FDA Guidance Documents **(includes a Form FDA 3654 for performance testing reference standard)**	10
Executive Summary	11
Device Description	12
Substantial Equivalence	13
Labeling	14
Sterilization and Shelf Life	15
Biocompatibility **(includes a Form FDA 3654 for biocompatibility reference standard)**	16
Software (This section does not apply.)	17
Electromagnetic Compatibility and Electrical Safety (This section does not apply.)	18
Performance, Bench	19
Performance, Animal (This section does not apply.)	20
Performance, Clinical **(includes Form FDA-3674)**	21

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Indications for Use

510(k) Number (if known): _____

Device Name: ULTRA Surgical Gowns and ULTRA Fluid Barrier Surgical Gowns

Indications for Use:

The Kimberly-Clark* ULTRA Surgical Gowns and ULTRA Fluid Barrier Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Fluid Barrier Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

A56

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

510(k) Summary for the ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown

Intended Use: The Kimberly-Clark* ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gown meets Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Fluid Barrier Surgical Gown meets Level 4 of the AAMI Liquid Barrier classifications.

Device Description: The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown are full-length, nonwoven SMS polypropylene gowns. They are constructed with raglan sleeves, hook-and-loop neck closures, and tie waist closures. The ULTRA Fluid Barrier Surgical Gown is film-reinforced for higher barrier protection. The ULTRA Surgical Gown fully meets the Association for the Advancement of Medical Instrumentation (AAMI) Level 3 requirements for liquid barrier performance. The ULTRA Fluid Barrier Surgical Gown fully meets the AAMI Level 4 requirements for liquid barrier performance.

Substantial Equivalence: The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown are substantially equivalent to the predicate Kimberly-Clark KIMGUARD* and SPUNGUARD* Surgical Gowns in intended use, design, materials, and biocompatibility attributes. The performance attributes of the ULTRA gowns are substantially equivalent to the predicate gowns with the exception that the ULTRA Surgical Gown meets the requirements of AAMI Level 3 liquid barrier requirements and the ULTRA Fluid Barrier Surgical Gown meets the requirements of AAMI Level 4 liquid barrier requirements. The ULTRA gowns and their predicates are provided sterile and for single use.

Summary of Testing: The ULTRA Surgical Gown has been tested in compliance with the requirements of Level 3 liquid barrier performance requirements of ANSI/AAMI PB70: 2003 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities." The ULTRA Fluid Barrier Surgical Gown has been tested in compliance with the requirements of Level 4 liquid barrier performance requirements of ANSI/AAMI PB70: 2003. The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown also meet the requirements of the National Fire Protection Association (NFPA) Test Method 702-1980 for Class I. The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown have been tested in compliance with the biocompatibility requirements of ISO 10993 for surface devices with limited contact with breached or compromised surfaces.

* Registered Trademark or Trademark of Kimberly-Clark Worldwide, Inc. or its affiliates.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as the Associate Director of Regulatory Affairs of Kimberly-Clark Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

(Typed Name)

David M. Lee

(Date) 3/17/08

David M. Lee
Associate Director of Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, GA 30076
770 587 7167

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Section 8. Class III Summary and Certification

This section does not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Section 9. Financial Certification or Disclosure Statement

This section does not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

A60

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Section 10. Use of Consensus Standards and FDA Guidance Documents

SUMMARY OF USE OF CONSENSUS STANDARDS

The ULTRA Surgical Gown was tested and met the acceptance criteria for the AAMI Level 3 liquid barrier classification for both impact penetration and hydrostatic pressure as indicated in AAMI / ANSI PB70:2003, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*. The ULTRA Fluid Barrier Surgical Gown was tested and met the acceptance criteria for the AAMI Level 4 liquid barrier classification for viral penetration as indicated in the standard, with testing according to ASTM1671:2003 *Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system.* Testing incorporated sample sizes ensuring an AQL of 4% as required by the standard. The Declaration of Conformity with a corresponding Form FDA 3654 is attached in this section.

SUMMARY REPORT ON ADHERENCE TO SURGICAL GOWN FDA GUIDANCE

This Abbreviated 510(k) also relies on adherence to the current FDA guidance document on surgical gowns - *Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes* (August 1993). This guidance was used to identify the information that FDA considers appropriate for marketing authorization for surgical gowns.

CONFIDENTIAL

Table 10-1. Adherence to FDA 1993 Surgical Gown Guidance, Section II – *Content and Organization of Information in a 510(k)*

Key Sections of FDA Guidance	Adherence within this Abbreviated 510(k)	Deviations from Guidance
A. Cover Letter	Section 1 *Cover Letter*	No deviations
B. Table of Contents	Section 4 *Table of Contents*	No deviations
C. Labels and Labeling	Section 14 *Labeling*	No deviations
D. Standards	• AAMI / ANSI PB70:2003 for liquid barrier performance as described here in Section 10 • Reference Standards for physical and mechanical attributes described in Tables 12.3 and 12.4 in Section 12 *Device Description* • Flammability Standard described in Section 19 *Performance, Bench*	No deviations
E. Device Description: 1. Description and Drawings:	Description in Table 12.1 and Drawings in Section 12 *Device Description*	No deviations

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Key Sections of FDA Guidance	Adherence within this Abbreviated 510(k)	Deviations from Guidance
E. Device Description: 2. Intended Use	• Indications for Use Statement in Section 5 • Description in Table 12.1 of Section 12 *Device Description*	No deviations
E. Device Description: 3. Specifications	• Physical Attributes in Table 12.3 of Section 12 *Device Description* • Mechanical Attributes in Table 12.4 of Section 12 *Device Description* • Biocompatibility Specifications in Section 16 *Biocompatibility*	No deviations
E. Device Description: 4. Complete listing of all materials used in fabricating the gowns	Table 12.2 of Section 12 *Device Description*	No deviations
F. Descriptive comparison to a legally marketed device	Section 13 *Substantial Equivalence*	No deviations
G. Performance Data Supporting Substantial Equivalence	• Descriptive data supports substantial equivalence, as the predicate Kimberly-Clark surgical gown and drape 510(k)s did not require the filing of significant performance data • Biocompatibility data in Section 16 *Biocompatibility* demonstrate that the gowns meet current industry standards for biocompatibility, as did the predicate gowns during their filings	No deviations
H. Sterility Information	The following information is provided in Section 15 *Sterilization and Shelf Life:* • Sterilization method • A description of the sterilization validation method and reference standard • SAL • Description of the packaging • Maximum Levels of residues of ethylene oxide and ethylene chlorohydrin	No deviations
I. 510(k) Summary	Section 6 *510(k) Summary*	No deviations

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Declaration of Conformity to AAMI / ANSI PB70:2003

Recognized consensus standard met:	AAMI / ANSI PB70:2003, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Specific sections followed for the referenced surgical gowns ♦ Section 4.1 Labeling Requirements ♦ Section 4.2.1 Barrier performance for Level 3 classification (ULTRA Surgical Gown) and Level 4 classification (ULTRA Fluid Barrier Surgical Gown) ♦ Section 4.2.3 Construction as described in 4.2.3.1 for surgical gowns. The entire front of the gown (Zones A, B, and C as described in Figure B.1 of the standard) has the liquid barrier performance claimed. Seams between these protective areas have the barrier performance claimed for the gown. ♦ Section 5 Tests, regarding Level 3 and 4 barrier performance as applicable to the gown tested. Gowns were tested at an AQL of 4.
Specification for the consensus standard that all requirements were met:	All requirements of the standard's sections applicable to surgical gowns, as listed above, were met for Level 3 or Level 4 liquid barrier performance classification, as applicable to the gown tested.
An identification of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed:	Not applicable. The applicable sections of the standard listed above were followed directly.
An identification of any requirements that were not applicable to the device:	The requirements for isolation gowns were not applicable. The requirements for surgical drapes and drape accessories were not applicable.
A specification of any deviations from the standard that were applied:	Not applicable. The applicable sections of the standard listed above were followed directly for barrier classification.

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A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference:	Not applicable. The tested device is the same as the device to be marketed.
The name and address of any test laboratory or certification body involved in determining the conformance of the device with the standard:	For AAMI Liquid Barrier Level 3 Tests: (b)(4) Third Party Information [redacted] For AAMI Liquid Barrier Level 4 Test: (b)(4) Third Party Information [redacted]

Certified by: (b)(6) [redacted]
Print name: [redacted]
Sign name: [redacted]
Title: Kimberly-Clark, P T&D Manager
Date: March 6, 2018

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Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]
AAMI / ANSI PB70:2003, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 014	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301) 443-1090 EF

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

ANDARD TITLE
AAMI / ANSI PB70:2003, LIQUID BARRIER PERFORMANCE AND CLASSIFICATION OF PROTECTIVE APPAREL AND DRAPES INTENDED FOR USE IN HEALTH CARE FACILITIES.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	Labeling Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
no deviation

DESCRIPTION
Labeling Requirements for the surgical gowns were followed, including labeling of the gown itself, package labeling, technical information and education.

JUSTIFICATION
There were no deviations or options requiring justification.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2.1 and 5	Section 4.2.1 Barrier Performance and Section 5 Tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
no deviation

DESCRIPTION
Barrier performance was followed according to Table 1: Level 3 for ULTRA Surgical Gowns and Level 4 for ULTRA Fluid Barrier Surgical Gowns. Gowns were tested at an AQL of 4.

JUSTIFICATION
There were no deviations or options requiring justification.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2.3.1	Construction, Surgical gowns and other protective apparel	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
no deviation

DESCRIPTION
The entire front of the gown (Zones A, B, and C as described in Figure B.1 of the standard) has the liquid barrier performance claimed. Seams between these protective areas have the barrier performance claimed for the gown.

JUSTIFICATION
There were no deviations or options requiring justification.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
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Section 11. Executive Summary

This Abbreviated 510(k) concerns the premarket notification for a product family of Kimberly-Clark* surgical gowns, labeled as either AAMI Liquid Barrier Level 3 for the ULTRA Surgical Gowns or AAMI Liquid Barrier Level 4 for the ULTRA Fluid Barrier Surgical Gowns. The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown are substantially equivalent to the predicate Kimberly-Clark KIMGUARD* and SPUNGUARD* Surgical Gowns in intended use, design, materials, and biocompatibility attributes. The performance attributes of the ULTRA gowns are substantially equivalent to the predicate gowns with the exception that the ULTRA Surgical Gown meets the requirements of AAMI Level 3 liquid barrier requirements and the ULTRA Fluid Barrier Surgical Gown meets the requirements of AAMI Level 4 liquid barrier requirements. This Abbreviated 510(k) focuses primarily on conformity to a recognized consensus standard and on adherence to FDA's guidance on surgical gown premarket notification submissions.

The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown are full-length, nonwoven SMS polypropylene gowns. They are constructed with cuffed sleeves, neck closures, and tie waist closures. The ULTRA Fluid Barrier Surgical Gown is film-reinforced for higher barrier protection.

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Section 12. Device Description

The purpose of this 510(k) is to allow Kimberly-Clark* to market the ULTRA Surgical Gown with an AAMI Level 3 Barrier Claim and the ULTRA Fluid Barrier Surgical Gown with an AAMI Level 4 Barrier Claim.

The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown are substantially equivalent to the predicate Kimberly-Clark KIMGUARD* and SPUNGUARD* Surgical Gowns in intended use, design, materials, and biocompatibility attributes. The performance attributes of the ULTRA gowns are substantially equivalent to the predicate gowns with the exception that the ULTRA Surgical Gown meets the requirements of AAMI Level 3 liquid barrier requirements and the ULTRA Fluid Barrier Surgical Gown meets the requirements of AAMI Level 4 liquid barrier requirements. The ULTRA gowns and their predicates are provided sterile and single use. Device attributes of the gowns are summarized in tables below.

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Table 12.1 General Device Description

Attribute	ULTRA Surgical Gowns (AAMI Fluid Barrier Level 3)	ULTRA Fluid Barrier Surgical Gowns (AAMI Fluid Barrier Level 4)
FDA Classification Code	FYA	FYA
FDA Device Class	Class 2	Class 2
Common Device Name	surgical gown	surgical gown
Indications for Use	The Kimberly-Clark* ULTRA Surgical Gowns and ULTRA Fluid Barrier Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Fluid Barrier Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.	
How Supplied	Sterile, single use, disposable	
Construction	(b)(4) [redacted]	

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Attribute	ULTRA Surgical Gowns (AAMI Fluid Barrier Level 3)	ULTRA Fluid Barrier Surgical Gowns (AAMI Fluid Barrier Level 4)
	(b)(4) [redacted] (b)(4)	
Product Family	ULTRA Surgical Gowns are available in Small, Large, X-Large, and XX-Large	ULTRA Fluid Barrier Surgical Gowns in Large, X-Large, and XX-Large

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Table 12.2 List of Surgical Gown Components

Component	ULTRA Surgical Gowns (AAMI Fluid Barrier Level 3)	ULTRA Fluid Barrier Surgical Gowns (AAMI Fluid Barrier Level 4)
Outer Facing	Not applicable	(b)(4) [redacted]
Outer Facing Adhesive	Not applicable	
Neck Binding Pigments	(b)(4) [redacted]	
Fabric		
Cuff		
Neck Closure, Loop		
Neck Closure, Hoop		
Adhesive		
Back Tie Tape		
Front Tie Tape		
Thread		
Ink		
Blue pigment		
White pigment		
Anti-Stat treatment		
Repellency treatment		

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Table 12.3 Physical Attributes

Attributes	Reference Standard	ULTRA Surgical Gowns (AAMI Fluid Barrier Level 3)	ULTRA Fluid Barrier Surgical Gowns (AAMI Fluid Barrier Level 4)
Basis Weight	ASTM[1] D3776 -07 Standard Test Methods for Mass Per Unit Area (Weight) of Fabric	(b)(4) [redacted] (ounces per square yard)	
Resistance to blood and liquid penetration	• ANSI/AAMI PB70:2003 *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* • AATCC 42:2000 *Water resistance: Impact penetration test* • AATCC 127:1998 *Water resistance: Hydrostatic pressure test*	The entire front of the gown (critical zones A, B, and C) must meet the following at AQL 4.0: Pass Spray Impact ≤ 1.0 g Pass Hydrostatic Head ≥ 50 cm	Not applicable
	• ANSI/AAMI PB70:2003 *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* • ASTM F1671:2003	Not applicable	The entire front of the gown (critical zones A, B, and C) must meet the following at AQL 4.0: Pass ASTM F 1671

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[1] American Society for Testing and Materials (international)

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Table 12.4 Mechanical Design Attributes

Attributes	Reference Standard	ULTRA Surgical Gowns (AAMI Fluid Barrier Level 3)	ULTRA Fluid Barrier Surgical Gowns (AAMI Fluid Barrier Level 4)
Grab Tensile Strength, CD/MD[2]	ASTM D 5034-95 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	(b) lbf	
Static Dissipation	INDA[3] Standard Test Methods IST 40.2-01 Electrostatic Decay of Nonwoven Fabrics	≤ (b) seconds	
Flame Resistance of NonWoven Fabrics (30 second burn challenge)	NFPA[4] 702-1980, specifications for fabrics without raised-fiber surfaces.	≥ (second flame spread time (Corresponds to the acceptance criteria of NFPA 702-1980 for Class 1, slow burning fabrics with a flame spread time of 20 seconds or more)	
Linting	INDA Standard Test Methods IST 160.1-01 Resistance to Linting of Nonwoven Fabric (Dry)	≤ (b) particles, 10.0 micron in diameter	≤ (b) particles, 10.0 micron in diameter

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[2] CD = Cross direction orientation of the fabric, in relation to machine direction (MD) during manufacture
[3] Association of the Nonwoven Fabrics Industry
[4] National Fire Prevention Association

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Section 13. Substantial Equivalence Discussion

The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown are substantially equivalent to the predicate Kimberly-Clark KIMGUARD* and SPUNGUARD* Surgical Gowns in intended use, design, materials, and biocompatibility attributes. The performance attributes of the ULTRA gowns are substantially equivalent to the predicate gowns with the exception that the ULTRA Surgical Gown meets the requirements of AAMI Level 3 liquid barrier requirements and the ULTRA Fluid Barrier Surgical Gown meets the requirements of AAMI Level 4 liquid barrier requirements. The ULTRA gowns and their predicates are provided sterile and single use.

Table 13.1 Substantial Equivalence Comparison

Attribute	**Predicate K781682 Kimberly-Clark* KIMGUARD* Surgical Gowns and Drapes**	**Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Drapes, Gowns & Packs**	**Subjects of this 510(k): ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown**
Classification Code	FYA	KKX (Note KKX, which is a surgical drape code, was likely assigned to this 510(k) by FDA as the submission consisted of a bundle of drapes, gowns, and surgical packs)	FYA
FDA Device Class	Class 2	same	same
Common Device Name	Surgical gown, sterile	same	same
Trade Name	KIMGUARD* Surgical Gown	SPUNGUARD* Surgical Gown	ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown
Indications for Use	KIMGUARD* Surgical Gowns are sterile, disposable products for use by operating room personnel during surgical procedures.	same	*Equivalent use, but the Indications for Use have been updated to reflect current industry focus on gown barrier properties and in accordance with 21 CFR 878.4040 as follows:* The Kimberly-Clark* ULTRA Surgical Gowns and ULTRA Fluid Barrier Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate

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Attribute	Predicate K781682 Kimberly-Clark* KIMGUARD* Surgical Gowns and Drapes	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Drapes, Gowns & Packs	Subjects of this 510(k): ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown
			material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Fluid Barrier Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.
How supplied	Single use, sterile, disposable, with or without towel	same	same
Gown color	Blue	same	same
Gown sizes	Medium, Large	Small, Large, Extra-Large	Small, Large, X-Large, and XX-Large
Materials of construction	(b)(4) [redacted]	[redacted]	[redacted]
Performance Attributes	Fabric possesses bacterial barrier properties and repellency to aqueous fluids.	same	same: • ULTRA Surgical Gown meets AAMI Level 3 liquid barrier performance[1]. To meet this performance level, the gown was tested in compliance with the following: ○ AATCC 42 Spray Impact Test ○ AATCC 127Hydrostatic Head Test • ULTRA Fluid Barrier Surgical Gown meets AAMI Level 4 liquid barrier performance. To meet this performance level, the

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[1] AAMI / ANSI PB70:2003, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.*

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Attribute	Predicate K781682 Kimberly-Clark* KIMGUARD* Surgical Gowns and Drapes	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Drapes, Gowns & Packs	Subjects of this 510(k): ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown
			gown was tested for resistance to penetration by blood-borne pathogens in compliance with ASTM 1671[2].
	Claim of "relatively lint-free"	same	same: INDA Standard Test Method IST 160.1-01 Resistance to Linting of Nonwoven Fabric (Dry), ≤ (b [redacted] particles, 10.0 micron in diameter
Safety Attributes	Met industry standards for biocompatibility: short term muscle implant study, long term muscle implant study, intraperitoneal implant study, irritation	same	same: passed ISO 10993 biocompatibility testing for cytotoxicity, irritation, and sensitization
Durability	Device is labeled and intended for single use.	same	same
Latex free	Yes	same	same
Sterility	Sterile	same	same

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[2] ASTM1671:2003 *Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system.*

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Draft Representative
Case and Package Labels
for
ULTRA Surgical Gown

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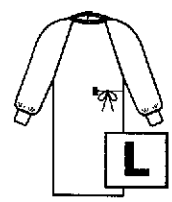
6"

6.75"

Kimberly-Clark*

ULTRA Surgical Gown, Large

with Polypropylene Fabric



AAMI Level 3

32

(32 x 1)

Single Use Only
Disposable

REF **95111 25**

Kimberly-Clark

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Sponsored in Australia by Kimberly-Clark Australia Pty Limited; 52 Alfred Street, Milsons Point, NSW 2061 • 1-800-101-021
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LOT

Expiration Date

Made in Honduras

00000000000

CE 0086

1"

11/12/07 • THERMAL CASE LABEL • 6" x 6.75"

BLUE items are preprinted on previously approved label shell

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ULTRA Surgical Gown
Large
REF 95111

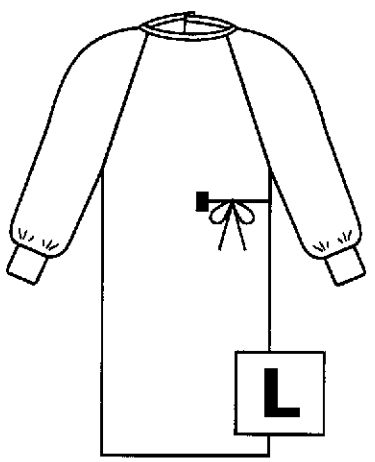
ULTRA Surgical Gown
Large
REF 95111

Kimberly-Clark*

REF 95111

ULTRA Surgical Gown, Large,

with Polypropylene Fabric,
with Towel



AAMI Level 3

EVOLUTION*

U.S. Patent Nos.: 5,213,881; 5,271,883; 5,484,688

Disposable; Flame Resistant NFPA 702 Class 1

Made in Honduras

99913 Rev 01

CE 0086

LOT

Expiration Date

(01) 1 06 80651 753130

Sterile • Natural Rubber Latex Free

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Cautions on Back • Précautions au dos • Sicherheitshinweise auf der Rückseite • Вниз предупреждения на задна страна • Consulte las precauciones al reverso • Upozornění na zadní straně • Advarsler på bagsiden • Hoiatused tagaküljel • Προειδοποιήσεις στην πίσω πλευρά • Avvertenze a tergo • Piesardzības norādījumi aizmugurē • Įspėjimai ant pakuotės nugarėlės • Figyelmeztetések a hátoldalon • Waarschuwingen op de achterkant • Varoitukset kääntöpuolella • Cuidados atrás • Avertisment pe verso • Мерки предпазливост на обратната страна • Upozornenia vzadu • Svarila na zadnej strane • Varnitukset kaantopuolella • Försiktighetsåtgärder på baksidan • Uyarılar ürün paketin arkasına bakınız • 注意事項在背面 • 注意事項は裏面にあります • 注意事項在背面

11/12/07
Form, Fill & Seal Package (primary package)
Black is in-line imprint
Blue is shell (top web) that has been previously approved

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Draft Representative
Case and Package Labels
for
ULTRA Fluid Barrier Surgical Gown

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

DRAFT COPY ONLY

6"

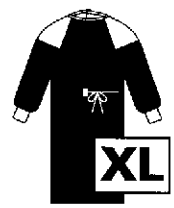
6.75"

[redacted]

Kimberly-Clark*

ULTRA Fluid Barrier Surgical Gown, X-Large,

with Film-Reinforced Polypropylene Fabric



AAMI Level 4

32

(32 x 1)

Single Use Only
Disposable

REF **95421 25**

Kimberly-Clark

Distributed in the U.S. by Kimberly-Clark Global Sales, LLC, Roswell, GA 30076 USA
In USA, please call 1-800-KCHELPS • www.kchealthcare.com
Kimberly-Clark, Roswell, GA 30076 USA; Kimberly-Clark N.V., Belgicastraat 13, 1930 Zaventem, Belgium
Sponsored in Australia by Kimberly-Clark Australia Pty Limited; 52 Alfred Street, Milsons Point, NSW 2061 • 1-800-101-021
輸入販売元：キンバリー・クラーク・ヘルスケア・インク　梅田市西区みなとみらい二丁目2番1号

STERILE EO

* Registered Trademark or Trademark of Kimberly-Clark Worldwide, Inc. © 2007 KCWW. All Rights Reserved. 20-01-504 0 06

LOT

Expiration Date

Made in Honduras

00000000000

CE 0086

1"

2/11/08 • THERMAL CASE LABEL • 6" x 6.75"

BLUE items are preprinted on previously approved label shell

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479

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ULTRA Fluid Barrier Gown
X-Large
REF 95421

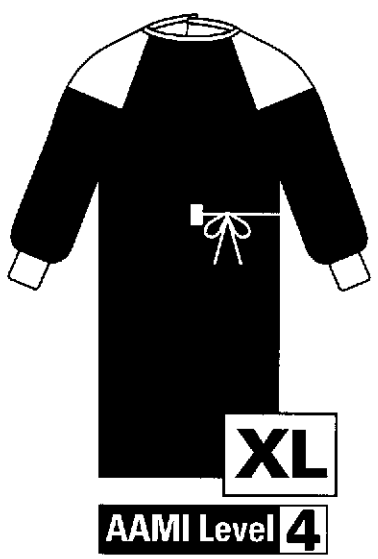
ULTRA Fluid Barrier Gown
X-Large
REF 95421

Kimberly-Clark

REF 95421

ULTRA Fluid Barrier Surgical Gown, X-Large,

with Film-Reinforced Polypropylene Fabric,
with Towel



EVOLUTION*
U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688
Disposable
Made In Honduras
91255 Rev 01

CE 0086

LOT

Expiration Date

(01) 1 06 80651 95421 9

Sterile • Natural Rubber Latex Free

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STERILE EO

Single Use Only

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[illegible]

Cautions on Back • Précautions au dos • Sicherheitshinweise auf der Rückseite • Вже предупреждения на гърба • Consulte las precauciones al reverso • Upozornění na zadní straně • Advarsler på bagsiden • Hoitusselosteet takaliitteen • Προειδοποιήσεις στην πίσω πλευρά • Avvertenze a tergo • Piesardzības noteikumi aizmugurē • Įspėjimai ant pakuotės nugarėlės • Figyelmeztetések a hátoldalon • Waarschuwingen op de achterkant • Forsiktighetsregler finnes på baksiden • Przestrogi na tyle • Cuidados atrás • Avertismente pe verso • Мерки предпазливост на обратната страна • Upozornenia vzadu • Svarila na zadnej strane • Varoitukset kaantopuolella • Försiktighetsåtgärder på baksidan • Uyarılar için paketin arkasına bakınız • 注意事項は裏面 • 注意事項在背面

2/11/08
Form, Fill & Seal Package (primary package)
Black is in-line imprint
Blue is shell (top web) that has been previously approved

DRAFT COPY ONLY

480

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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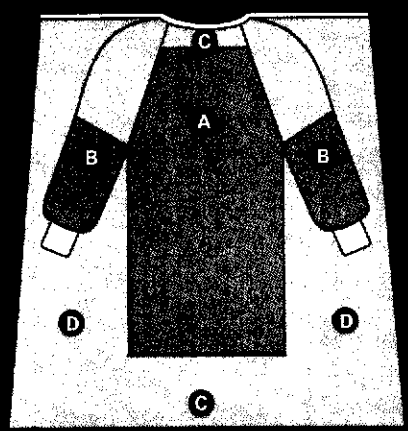
Draft Informational Brochure
for the ULTRA Surgical and ULTRA Fluid Barrier Gowns

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

DRAFT



AAMI Liquid Barrier Standard: Now for ULTRA Surgical Gowns

- **AAMI Level 3:**

  ULTRA Surgical Gowns provide Level 3 liquid barrier in zones A, B, and C

- **AAMI Level 4:**

  The ULTRA Fluid Barrier Surgical Gowns provide Level 4 liquid barrier in zones A, B, and C

[1]ANSI/AAMI PB70:2003 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

KIMBERLY-CLARK* ULTRA Gowns Meet AAMI Liquid Barrier Standard[1]

The liquid barrier standard for classification of protective apparel and drapes for use in hospital facilities has been introduced by the Association for the Advancement of Medical Instrumentation (AAMI) to assist healthcare personnel in the selection and use of surgical gowns, drapes, and other protective apparel.

The AAMI Liquid Barrier Standard is used widely and is now recognized by the FDA as a standard for barrier testing, classification, performance claims, and product labeling of surgical gowns.

AAMI: Defining the Critical Zones

AAMI liquid barrier performance levels are classified from Level 1 through Level 4, with Level 4 being the highest liquid barrier level. These levels apply to the product's Critical Zones. For surgical gowns, the critical zones are, at a minimum, the front area of the gown from chest to knees (area A) and the sleeves from the cuff to above the elbow (area B). The standard requires that the entire front of a surgical gown (Areas A, B, and C) provide a liquid barrier of at least Level 1. The back of the gown (area D) may be non-protective.

AAMI Classification of liquid barrier performance of surgical gowns, surgical drapes and drape accessories

Level	Test	Description	Result	AQL requirement
1	AATCC 42:2000	Impact penetration	≤ 4.5 g	4%
2	AATCC 42:2000 AATCC 127:1998	Impact penetration Hydrostatic pressure	≤ 1.0 g ≥ 20 cm	4% 4%
3	AATCC 42:2000 AATCC 127:1998	Impact penetration Hydrostatic pressure	≤ 1.0 g ≥ 50 cm	4% 4%
4	ASTM F1671:2003	Resistance to bacteriophage (surgical gowns and other protective apparel)	Pass	4%
	ASTM F1670:2003	Resistance to synthetic blood (surgical drapes and drape accessories)	Pass	4%

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A22

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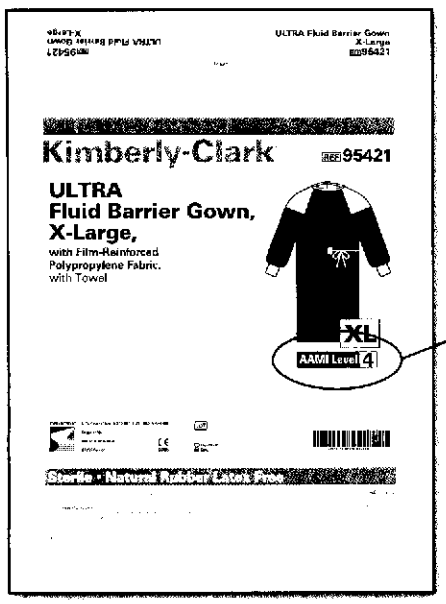
DRAFT



"At the shelf" selection is where AAMI liquid barrier classification provides its greatest benefit, through informative product labeling. You will find the AAMI level clearly indicated on each gown package and case label. In addition, the AAMI level is stamped on the inside of each gown.

"Surgical gowns and drapes should be resistant to penetration by blood and other bodily fluids as necessitated by their intended use. Ultimately, blood and other bodily fluids are vehicles for bacterial and viral transmission."

— AORN 2004 Standards, Recommended Practices and Guidelines

Commitment to Excellence

If, for any reason, our products do not meet your expectations, please let us know your comments or suggestions for improvement. Your input will result in a concerted effort on our part to meet your requirements. Our goal is to provide quality products that completely meet your needs time after time.

For more information, please call your sales representative, or visit our web site at www.kchealthcare.com.

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H0707-07-01

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H23

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Section 15. Sterilization and Shelf Life

The Ultra Surgical Gowns are sterilized by ethylene oxide (EO) with a Sterility Assurance Level (SAL) of 10^{-6}. The ethylene oxide sterilization of the surgical gowns was validated according to ANSI/AAMI/ISO 11135-1:2007 *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.* Ethylene oxide residuals were validated as being within the acceptance criteria according to ANSI/AAMI/ISO 10993-7:1995 *Biological evaluation of medical devices, Part 7: Ethylene oxide sterilization residuals, Section 4.3.3 Limited Exposure Devices*, as summarized in Table 15-1.

Table 15-1. Summary of EO Residuals Validation for the ULTRA Surgical Gowns

EO Residual	Acceptance Criteria	ULTRA Surgical Gowns (AAMI Level 3)	ULTRA Fluid Barrier Surgical Gowns (AAMI Level 4)
(b)(4) [redacted]			

The ULTRA Surgical Gowns are provided in a (b)(4) [redacted].

The surgical gowns have been validated for performance over a shelf life of 1 year, and will be labeled with 1 year shelf life while Kimberly-Clark completes the shelf life testing protocol for 3 and 5 year shelf life. Upon successful completion of the accelerated aging testing for each time point, Kimberly-Clark will extend the shelf life duration on the product labeling. The protocol for the shelf life testing is attached to this section. Note, the protocol was initiated prior to the development team's final choice on the gowns' trade names. Therefore, in the shelf life protocol, the Ultra Surgical Gown (AAMI Barrier Level 3) is called "Ultra Non-Reinforced" and the Ultra Fluid Barrier Gown (AAMI Barrier Level 4) is called "Ultra Impervious", though these names in the protocol will not be used to market the gowns.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Drawings

Representative
ULTRA Surgical Gown

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Drawings

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Drawing

Representative
ULTRA Fluid Barrier Surgical Gown

Note, the attached drawing was initiated prior to the development team's final choice on the gown's trade name. Therefore, in the title of the drawing, the Ultra Fluid Barrier Gown (AAMI Barrier Level 4) is called "Ultra Impervious", though this name in the drawing will not be used to market the gown.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Drawings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Third Party Testing

(b)(4) Third Party Testing

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(b)(4) Third Party Testing

(b)(4) Third Party Testing

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Section 16. Biocompatibility

Both the ULTRA Surgical Gown and the ULTRA Fluid Barrier Surgical Gown were tested separately for biocompatibility in accordance with ISO 10993-1:2003E Biological Evaluation of Medical Devices Part 1 – Evaluation and Testing using the guidelines for surface contact devices that may contact breached surfaces for less than 24 hours. Final finished sterilized gowns were tested. All testing was performed in accordance with GLP. Biocompatibility testing is summarized in Tables 16-1 and 16-2. All biocompatibility results for both gowns met acceptance criteria.

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Table 16-1. Biocompatibility Results for ULTRA Surgical Gown

Test Type	Ref Standard Described in Report	Acceptance Criteria	Test Result	Test Report Identification
(b)(4) [redacted]				

Table 15-2. Biocompatibility Results for ULTRA Fluid Barrier Surgical Gown

Test Type	Ref Standard Described in Report	Acceptance Criteria	Test Result	Test Report Identification
(b)(4) [redacted]				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016
Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]
AAMI / ANSI / ISO 10993 Biological evaluation of medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 018	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices May 1, 1995 (G95-1)

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

ANDARD TITLE
AAMI / ANSI / ISO 10993 BIOLOGICAL EVALUATION OF MEDICAL DEVICES

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 5:1999, 8.2	Tests for In Vitro Cytotoxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
Option selected: MEM Elution. No deviations.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 10:2002, 5.2.4.3 and 7.1	Tests for irritation and delayed-type hypersensitivity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
ns selected: Irritation according to 5.2.4.3 and Sensitization according to 7.1. No deviations.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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ULTRA Surgical Gown

(b)(4) [redacted]

T ti

494

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Third Party Testing

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Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Surgical Gown

(b)(4) [redacted]

T ti

520

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 17. Software

This section does not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Section 18. Electromagnetic Compatibility and Electrical Safety

This section does not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 19 Performance Bench

(b)(4) Testing

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Testing

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Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Section 20. Performance Testing, Animal

This section does not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 21. Performance Testing, Clinical

This section does not apply.

Form FDA-3674 is attached.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647, Released by CDRH on 08-26-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Kimberly-Clark Corporation

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
03/13/2008

3. ADDRESS *(Number, Street, State, and ZIP Code)*
1400 Holcomb Bridge Road
Roswell, GA 30076

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 770-587-7167
(Fax) 770-587-7752

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

surgical gown, FYA, Class 2

ULTRA Surgical Gowns

ULTRA Fluid Barrier Surgical Gowns

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
David M. Lee

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) David M. Lee
(Title) Associate Director of Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, GA 30076

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 770-587-7167
(Fax) ~~770-587-7752~~ 920 969 5160

15. DATE OF CERTIFICATION
03/13/2008

PSC Graphics: (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Kapil Panguuri

Subject: 510(k) Number K080795/S2

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓

Rev. 7/2/07

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*	
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*	

Regulation Number	Class*	Product Code
21 CFR 878.4040	II	FYA

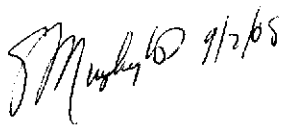
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Shala R Murphy MD (Branch Chief) JMCB (Branch Code) 9/2/08 (Date)

Final Review: JN Annie Cox Acting MD for CC (Division Director) Acting Deputy (Date) 9/3/08

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016



Premarket Notification [510(k)] Review
K080795

Date: September 2, 2008
To: The Record
From: Kapil Panguluri, Ph.D.

Office: ODE
Division: DAGID

510(k) Holder: Kimberly-Clark Corporation, 1400 Holcomb Bridge Road, Roswell, Georgia 30076
Device Name: 1. Ultra Surgical Gown
2. Ultra Film-Reinforced Surgical Gown
Contact: Mr. David Lee, 1400 Holcomb Bridge Road, Roswell, Georgia 30076
Phone: (770) 587-7167
Fax: (920) 225-4784
Email: David.Lee@kcc.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Ultra Surgical Gown with AAMI Liquid Barrier Level 3 claim and Ultra Film-Reinforced Surgical Gown with AAMI Liquid Barrier Level 4 claims into interstate commerce.

The first two cycles of this submission were reviewed by Mr. Terrell Cunningham (Lead Reviewer) (see memos dated May 13, 2008 and June 13, 2008). In the S1 cycle the lead reviewer had identified three deficiencies with the submission and the following is the review of the responses provided by the firm and a recommendation towards substantial equivalence to the predicate surgical gowns.

II. Administrative Requirements:

	Yes	No	N/
Indications for Use page (Indicate if: Prescription or OTC)	✓		
Truthful and Accuracy Statement	✓		
510(k) Summary	✓		
Standards Form	✓		

III. Device Description:

	Yes	No	N/
Is the device life-supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?		✓	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Yes	No	N/
Does the device design use software?		✓	
Is the device sterile?	✓		
Is the device reusable (not reprocessed single use)?		✓	
Are "cleaning" instructions included for the end user?			

For Device description see original memo dated June 13, 2008.

IV. INDICATIONS FOR USE: "The Kimberly-Clark Ultra Surgical Gown and Ultra Film-Reinforced Surgical Gown are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids and particulate material. The Ultra Surgical Gown meets Level 3 of the AAMI Liquid Barrier classifications and the Ultra Film-Reinforced Surgical Gown meets Level 4 of the AAMI Liquid Barrier classifications".

The 510(k) summary statement continues to show one of the subject devices as Ultra Fluid Barrier Surgical Gown. The firm was asked to revise the summary statement and provide us a copy for our review. On September 2, 2008 the firm in its email provided with a revised copy of 510(k) summary statement. *Response is acceptable.*

V. PREDICATE DEVICE COMPARISON: For Predicate Device comparison see original memo dated June 13, 2008.

(b)(4) Deficiencies

[redacted]

VI. PHYSICAL PERFORMANCE/SPECIFICATIONS:

Device specifications can be found in the memo dated June 13, 2008. All performance issues are deemed to be acceptable.

PERFORMANCE TESTING (BENCH): The performance testing data is deemed to be adequate (see Lead Reviewer's memo dated June 13, 2008).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PERFORMANCE TESTING (ANIMAL): All biocompatibility test results are deemed to be acceptable (see Lead Reviewer's memo dated June 13, 2008).

VII. **STERILIZATION:** The original review of sterilization specifications for the subject device did not identify any concerns. However in the original 510(k) submission (b)(4) Deficiencies

(b)(4) Deficiencies

[redacted]

VII. BIOCOMPATIBILITY: See Performance Testing (Animal).

VIII. STANDARDS: Although the firm provided FDA Standards Data Report form for 510(k)s however (b)(4) Deficiencies

(b)(4) Deficiencies

[redacted]

IX. LABELING: For description of the labeling see original memo dated June 13, 2008. In the S1 review of this submission the lead reviewer identified the following concerns regarding the labeling of the device.

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Deficiencies

[redacted]

IX: DEFICIENCIES: None.

X. SUBSTANTIAL EQUIVALENCE DISCUSSION:

	Yes	No	
1. Same Indication Statement?	✓		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	✓		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		✓	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	✓		If **NO** = Request Data
9. Data Demonstrate Equivalence?	✓		Final Decision: **SE**

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

X. RECOMMENDATION: It is recommended for consideration of substantial equivalence to the legally marketed predicate surgical gowns K781682 and K842115.

Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA

Kapil Panguluri, Ph.D. — September 2, 2008
Reviewer — Date

Branch Chief — 9/2/08
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Panguluri, Ramesh K

From: Lee, David [David.Lee@kcc.com]
Sent: Tuesday, September 02, 2008 3:55 PM
To: Panguluri, Ramesh K
Cc: Kozma, Thomas
Subject: K080795
Attachments: Revised 510(k) SUMMARY .doc; Revised Indications for Use Statement.doc

Dear Mr. Panguluri,

Pursuant to your phone request today regarding K080795 please find attached the following documents:

(b)(4) Deficiencies

[redacted]

Please let me know if you need any additional information. Thanks!

Regards,
David

David M. Lee
ssociate Director of Regulatory Affairs
mberly-Clark HealthCare
1400 Holcomb Bridge Road
Building 300, #1159
Roswell, GA 30076
770 587 7167 off
920 225 4784 fax
David.lee@kcc.com

This e-mail is intended for the use of the addressee(s) only and may contain privileged, confidential, or proprietary information that is exempt from disclosure under law. If you have received this message in error, please info promptly by reply e-mail, then delete the e-mail and destroy any printed copy Thank you.

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Indications for Use

510(k) Number (if known): **K080795**

Device Name: ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns

Indications for Use:

The Kimberly-Clark* ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Addendum:

The ULTRA Surgical Gowns AAMI Level 3 are available under the following Reference Numbers:

- 95101 ULTRA Surgical Gown, Small
- 95111 ULTRA Surgical Gown, Large
- 95121 ULTRA Surgical Gown, X-Large
- 95055 ULTRA Surgical Gown, Large (2 Pack)
- 95131 ULTRA Surgical Gown, XX-Large

The ULTRA Film-Reinforced Surgical Gowns AAMI Level 4 are available under the following Reference Numbers:

- 95411 ULTRA Film-Reinforced Surgical Gown, Large
- 95421 ULTRA Film-Reinforced Surgical Gown, X-Large
- 95431 ULTRA Film-Reinforced Surgical Gown, XX-Large
- 95511 ULTRA Film-Reinforced Specialty Surgical Gown, Large
- 95521 ULTRA Film-Reinforced Specialty Surgical Gown, X-Large
- 95531 ULTRA Film-Reinforced Specialty Surgical Gown, XX-Large

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

510(k) Summary for the ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown

Intended Use: The Kimberly-Clark* ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gown meets Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gown meets Level 4 of the AAMI Liquid Barrier classifications.

Device Description: The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are full-length, nonwoven SMS polypropylene gowns. They are constructed with raglan sleeves, hook-and-loop neck closures, and tie waist closures. The ULTRA Film-Reinforced Surgical Gown is film-reinforced for higher barrier protection. The ULTRA Surgical Gown fully meets the Association for the Advancement of Medical Instrumentation (AAMI) Level 3 requirements for liquid barrier performance. The ULTRA Film-Reinforced Surgical Gown fully meets the AAMI Level 4 requirements for liquid barrier performance.

Substantial Equivalence: The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are substantially equivalent to the predicate Kimberly-Clark KIMGUARD* and SPUNGUARD* Surgical Gowns in intended use, design, materials, and biocompatibility attributes. The performance attributes of the ULTRA gowns are substantially equivalent to the predicate gowns with the exception that the ULTRA Surgical Gown meets the requirements of AAMI Level 3 liquid barrier requirements and the ULTRA Film-Reinforced Surgical Gown meets the requirements of AAMI Level 4 liquid barrier requirements. The ULTRA gowns and their predicates are provided sterile and for single use.

Summary of Testing: The ULTRA Surgical Gown has been tested in compliance with the requirements of Level 3 liquid barrier performance requirements of ANSI/AAMI PB70: 2003 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities." The ULTRA Film-Reinforced Surgical Gown has been tested in compliance with the requirements of Level 4 liquid barrier performance requirements of ANSI/AAMI PB70: 2003. The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown also meet the requirements of the National Fire Protection Association (NFPA) Test Method 702-1980 for Class I. The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown have been tested in compliance with the biocompatibility requirements of ISO 10993 for surface devices with limited contact with breached or compromised surfaces.

* Registered Trademark or Trademark of Kimberly-Clark Worldwide, Inc. or its affiliates.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Panguluri, Ramesh K

From: Lee, David [David.Lee@kcc.com]
Sent: Friday, August 29, 2008 3:54 PM
To: Panguluri, Ramesh K
Cc: Kozma, Thomas; Peacock, Lisa
Subject: K080795
Attachments: FDA-3654 10993-7.pdf; FDA-3654 11135.pdf; FDA 3654 10993.pdf; FDA 3654 barrier.pdf

Dear Mr. Panguluri,

Pursuant to your request regarding K080795 please find attached the following FDA Form 3654 for:

(b)(4) Deficiencies

[redacted]

Please let me know if you have any additional questions.
Regards,
David

David M. Lee
Associate Director of Regulatory Affairs
Kimberly-Clark HealthCare
1400 Holcomb Bridge Road
Building 300, #1159
Roswell, GA 30076
770 587 7167 off
920 225 4784 fax
David.lee@kcc.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☑ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-7:1995 (R) 2001, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residu

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-76 (010)		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 10993-7:1995 (R) 2001, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residu

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.3	Allowable Limits (4.3.3 Limited exposure devices)	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☑ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 11135-1:2007,Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development,

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3] # 14-228 (019)		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 11135-1:2007,Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development,

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex B	Conservative determination of lethal rate of the sterilization process-Overkill	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]
AAMI / ANSI / ISO 10993 Biological evaluation of medical devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 018	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices May 1, 1995 (G95-1)

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI / ANSI / ISO 10993 BIOLOGICAL EVALUATION OF MEDICAL DEVICES

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 5:1999, 8.2	Tests for In Vitro Cytotoxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊
Option selected: MEM Elution. No deviations.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 10:2002, 5.2.4.3 and 7.1	Tests for irritation and delayed-type hypersensitivity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊
ns selected: Irritation according to 5.2.4.3 and Sensitization according to 7.1. No deviations.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◊ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]
AAMI / ANSI PB70:2003, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 014	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
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 PSC Graphics (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI / ANSI PB70:2003, LIQUID BARRIER PERFORMANCE AND CLASSIFICATION OF PROTECTIVE APPAREL AND DRAPES INTENDED FOR USE IN HEALTH CARE FACILITIES.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	Labeling Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
no deviation

DESCRIPTION
Labeling Requirements for the surgical gowns were followed, including labeling of the gown itself, package labeling, technical information and education.

JUSTIFICATION
There were no deviations or options requiring justification.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2.1 and 5	Section 4.2.1 Barrier Performance and Section 5 Tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
no deviation

DESCRIPTION
Barrier performance was followed according to Table 1: Level 3 for ULTRA Surgical Gowns and Level 4 for ULTRA Fluid Barrier Surgical Gowns. Gowns were tested at an AQL of 4.

JUSTIFICATION
There were no deviations or options requiring justification.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2.3.1	Construction, Surgical gowns and other protective apparel	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*
no deviation

DESCRIPTION
The entire front of the gown (Zones A, B, and C as described in Figure B.1 of the standard) has the liquid barrier performance claimed. Seams between these protective areas have the barrier performance claimed for the gown.

JUSTIFICATION
There were no deviations or options requiring justification.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Terrell Cunningham

Subject: 510(k) Number K080795/S1

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

Rev. 7/2/07

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Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:

(Branch Chief) (Branch Code) (Date)

Final Review:

(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Premarket Notification [510(k)] Review
Abbreviated
K080795/S1

Date:	June 13, 2008	
To:	The Record	Office: ODE
From:	Terrell Cunningham, Nurse Consultant	Division: DAGID
Device Name:	K080795 ULTRA Surgical Gown and ULTRA Flim-Reinforced Surgical Gown	
Contact:	Mr. David Lee	
Firm:	Kimberly-Clark Corp.	
Phone:	770 587-7167	
Fax:	920 969-5160	
Email:	David.Lee@kcc.com	

I. Purpose and Submission Summary

The 510(k) holder, Kimberly-Clark Corp. has submitted a premarket notification for ULTRA Surgical Gown and ULTRA Flim-Reinforced Surgical Gown. The purpose of the submission is to declare conformity of the product to Association for the Advancement of Medical Instrumentation (AAMI) PB70:2003, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or **OTC**)	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Form	√		

STANDARDS REFERENCED:

1. AAMI PB7O, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, 2003
2. ISO 10993-5 , Biological Evaluation of Medical Devices -Part 5: Test for in Vitro and Cytotoxicity
3. ISO 10993-10, Biological Evaluation of Medical Devices -Part 10: Test for Irritation and Delayed-type Hypersensitivity.
4. ANSI/AAMI/ISO 11135-1 Sterilization of Healthcare Products – Ethylene oxide – Part1: Requirements for Development, Validation, and Routine Control of Ethylene Oxide Sterilization
5. "ANSI/AAMI/ISO 10993-7: Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals,"

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III. Device Description

The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown manufactured by Kimberly-Clark Corp. are full-length, (b)(4) [redacted] The ULTRA Film-Reinforced Surgical Gown is film-reinforced (b)(4) [redacted]) for added barrier protection. Graphic designs of the gowns were provided for review. The gowns are available in sizes small, medium, large and extra large. The sponsor claims that the ULTRA Surgical Gown meets the AAMI Level 3 requirements for liquid barrier performance and that the ULTRA Film-Reinforced Surgical Gown meets the AAMI Level 4 requirements for liquid barrier performance. The basic construction of the gowns and the device dimensions are provided for our review in Section 12 of the submission.

The firm has provided additional information regarding the content of this submission. There are a total of eleven (11) surgical gowns that are the subject of this submission. The following is a complete list of names and Reference (catalog) numbers.

Ultra Surgical Gowns AAMI Level 3:

- 95101 ULTRA Surgical Gown, Small
- 95111 ULTRA Surgical Gown, Large
- 95121 ULTRA Surgical Gown, X-Large
- 95055 ULTRA Surgical Gown, Large (2 Pack)
- 95131 ULTRA Surgical Gown, XX-Large

Ultra Film-Reinforced Surgical Gown AAMI Level 4:

- 95411 ULTRA Film-Reinforced Surgical Gown, Large
- 95421 ULTRA Film-Reinforced Surgical Gown, X-Large
- 95431 ULTRA Film-Reinforced Surgical Gown, XX-Large
- 95511 ULTRA Film-Reinforced Specialty Surgical Gown[1], Large
- 95521 ULTRA Film-Reinforced Specialty Surgical Gown, X-Large
- 95531 ULTRA Film-Reinforced Specialty Surgical Gown, XX-Large

Note: Surgical towel and the procedure pack have been deleted from this submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	
Is the device sterile?	√		
Is the device reusable (not reprocessed single use)?		√	
Are "cleaning" instructions included for the end user?			

IV. Indications for Use

The firm states that the indication for use for the device is as follows:
The Kimberly-Clark* ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gown meets Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gown meets Level 4 of the AAMI Liquid Barrier classifications.

As requested by the Agency, the sponsor has changed the name of the ULTRA Fluid-Barrier Gowns to ULTRA Film-Reinforced Surgical Gowns. Also, an attachment listing all of the model numbers has been provided for the Indication for Use Statement.

V. Predicate Device Comparison

The sponsor claims that their gowns are substantially equivalent to the predicate Kimberly-Clark KIMGUARD and SPUNGUARD Surgical Gowns in intended use, design, material, and biocompatibility attributes. The sponsor also claims that the performance attributes of the ULTRA gowns are substantially equivalent to the predicate gowns with the exception that the ULTRA Surgical Gown meets the requirements of AAMI Level 3 liquid barrier requirements and the ULTRA Fluid Barrier Surgical Gown meets the requirements of AAMI Level 4 liquid barrier requirements. The ULTRA surgical gowns and their predicates are provided sterile, single use. The referenced predicates have been previously cleared for market and was the subject of K781682 (Kimberly-Clark KIMGUARD Surgical Gowns and Drapes) and K842115 (Kimberly-Clark SPUNGUARD Surgical Drapes, Gowns and Packs). K781682 and K842115 are not available for review on IMAGE.

Recommendations: (b)(4) [redacted]

(b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

Recommend the sponsor be asked to provide the following:

(b)(4) [redacted]

VI. Labeling

Draft copies of labeling were provided for our review. The labeling provided for our review includes the following claims/statements:

The labeling for the ULTRA and ULTRA Film-Reinforced Surgical Gown provided for our review contains the following information:

- Manufacturer name and address
- Contents of the package (…Polypropylene Fabric/ with Film-Reinforced)
- Size
- Lot number
- Sterile-EO
- Single-Use
- Disposable
- Expiration Date
- AAMI Level 3/ AAMI Level 4
- Natural Rubber Latex Free
- Flame Resistant NFPA 702 Class 1
- Contents Sterile: Unless this package is opened or damaged

The firm has adequately addressed FDA concerns regarding following website: http://www.kca.com.au/healthcare/products/surgical-gowns.htm.

This submission contains several references to the term (b)(4) [redacted]

Recommendation: (b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

VII. Sterilization/Shelf Life/Reuse

The Ultra Surgical Gowns are sterilized by ethylene oxide (EO) with a Sterility Assurance Level (SAL) of 10-6. The ethylene oxide sterilization of the surgical gowns was validated according to ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices. Ethylene oxide residuals were validated as being within the acceptance criteria according to ANSI/AAMI/ISO 10993-7:1995 Biological evaluation of medical devices, Part 7: Ethylene oxide sterilization residuals, Section 4.3.3 Limited Exposure Devices, as summarized in the table below.

Summary of EO Residuals Validation

EO Residual	Acceptance Criteria	ULTRA Surgical Gowns	ULTRA Film-Reinforced Surgical Gowns
(b)(4) [redacted]			

The firm states that ULTRA Surgical Gowns are provided in (b)(4) b)(4) [redacted] (b)(4)

Sterilization Checklist

1. Sterilant:	YES	NO
a. Sterilization method description (e.g., Steam, ***EO***, Radiation):	X	
b. Dose, for radiation (e.g., 25 – 50 kGy):	N/A	
c. Sterilant residuals remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	X	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135))	ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products –Ethylene oxide-Part 1: Requirements for development, validation , and routine control of a sterilization process for medical devices.	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	X	
4. Is it labeled "Pyrogen Free"?		X
If so, a description of the method: (e.g., LAL (Limulus Amebocyte Lysate test))	N/A	
5. A description of the packaging (not including package integrity test data):	X	

The sponsor claims that the surgical gowns have been validated for performance over a shelf life of 1 year, and will be labeled with 1 year shelf life while they complete the shelf life testing protocol for 3 and 5 year shelf life. Upon successful completion of the accelerated aging testing for each time point, Kimberly-Clark has expressed the desire to ~~will~~ extend the shelf life duration on the product labeling. The protocol for the shelf life testing was provided for our review.

VIII. Biocompatibility

Refer to section XII Performance Testing – Animal, below.

IX. Software

Not applicable

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable

XI. Performance Testing – Bench

The firm claims that the Ultra Surgical Gowns have been evaluated in accordance with the test requirements for surgical gowns in AAMI PB70:2003.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Physical Attributes

Attributes	Reference Standard	ULTRA Surgical Gowns (AAMI Fluid Barrier Level 3)	ULTRA Fluid Barrier Surgical Gowns (AAMI Fluid Barrier Level 4)
Basis Weight	ASTM[1] D3776 -07 Standard Test Methods for Mass Per Unit Area (Weight) of Fabric	(b)(4) [redacted] (ounces per square yard)	
Resistance to blood and liquid penetration	• ANSI/AAMI PB70:2003 *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* • AATCC 42:2000 *Water resistance: Impact penetration test* • AATCC 127:1998 *Water resistance: Hydrostatic pressure test*	The entire front of the gown (critical zones A, B, and C) must meet the following at AQL 4.0: Pass Spray Impact ≤ 1.0 g Pass Hydrostatic Head ≥ 50 cm	Not applicable
	• ANSI/AAMI PB70:2003 *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* • ASTM F1671:2003	Not applicable	The entire front of the gown (critical zones A, B, and C) must meet the following at AQL 4.0: Pass ASTM F 1671

The sponsor claims that performance data demonstrating an AQL of 4%:

- The ULTRA Surgical Gown has been tested in compliance with the requirements of Level 3 liquid barrier performance requirements of ANSI/AAMI PB7O: 2003 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities."

- The ULTRA Film-Reinforced Surgical Gown has been tested in compliance with the requirements of Level 4 liquid barrier performance requirements of ANSI/AAMI PB7O: 2003.

3HH

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown also meet the requirements of the National Fire Protection Association (NFPA) Test Method 702-1980 for Class I.

Mechanical Design Attributes

Attributes	Reference Standard	ULTRA Surgical Gowns (AAMI Fluid Barrier Level 3)	ULTRA Fluid Barrier Surgical Gowns (AAMI Fluid Barrier Level 4)
Grab Tensile Strength, CD/MD[2]	ASTM D 5034-95 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	(b) [redacted] lbf	
Static Dissipation	INDA[3] Standard Test Methods IST 40.2-01 Electrostatic Decay of Nonwoven Fabrics	≤ [redacted] (b) seconds	
Flame Resistance of NonWoven Fabrics (30 second burn challenge)	NFPA[4] 702-1980, specifications for fabrics without raised-fiber surfaces.	≥ (b) [redacted] second flame spread time (Corresponds to the acceptance criteria of NFPA 702-1980 for Class 1, slow burning fabrics with a flame spread time of 20 seconds or more)	
Linting	INDA Standard Test Methods IST 160.1-01 Resistance to Linting of Nonwoven Fabric (Dry)	≤ (b)(4) [redacted], 10.0 micron in diameter	≤ (b) [redacted] particles, 10.0 micron in diameter

Conclusion: The performance testing data summaries provided are adequate.

XII. Performance Testing – Animal

The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown were tested in accordance with the biocompatibility requirements of ISO 10993 for surface devices with limited contact with breached or compromised surfaces. The firm states that the final finished sterilized gowns were tested. Copies of the actual test results were provide for our review. All biocompatibility test results are acceptable as summarized in the tables below:

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Table 16-1. Biocompatibility Results for ULTRA Surgical Gown

Test Type	Ref Standard Described in Report	Acceptance Criteria	Test Result	Test Report Identification
(b)(4) [redacted]				

Table 15-2. Biocompatibility Results for ULTRA Fluid Barrier Surgical Gown

Test Type	Ref Standard Described in Report	Acceptance Criteria	Test Result	Test Report Identification
(b)(4) [redacted]				

XIII. **Performance Testing – Clinical**: None provided. Not needed to determine substantial equivalence.

3H6

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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XI. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	√		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	√		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		√	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?		√	**If NO = Request Data**
9. Data Demonstrate Equivalence?			Final Decision:

Note: Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed: Performance test data/ revised declaration of conformity is needed to demonstrates that the device is or is not substantially equivalent to the predicate device.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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X. Deficiencies

(b)(4)

[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Deficiencies

[redacted]

XII. Recommendation: Recommend that K080795 ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns be placed on HOLD pending receipt of response from firm to our request for additional information.

Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA

Terrell A. Cunningham
Reviewer

Friday, June 13, 2008
Date

Dr. Sheila Murphey

4/13/08

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Premarket Notification [510(k)] Review

Abbreviated
K080795/S1

Date:	May 13, 2008	
To:	The Record	Office: ODE
From:	Terrell Cunningham, Nurse Consultant	Division: DAGID
Device Name:	K080795 ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown	
Contact:	Mr. David Lee	
Firm:	Kimberly-Clark Corp.	
Phone:	770 587-7167	
Fax:	920 969-5160	
Email:	David.Lee@kcc.com	

Our review of your 510(k) submission has identified several deficiencies that need to be resolved before we will be able to make a recommendation. To complete the review of this submission, please provide a response to the following:

(b)(4) Deficiencies

[redacted]

PLAN: Please provide this information within 30 days. Effective today, June 13, 2008, your submission has been placed on hold pending receipt of the above additional information. If you have any questions, please contact me by fax at 240-276-3789, phone at 240-276-3766, or by email at terrell.cunningham@fda.hhs.gov.

Cunningham

Terrell Cunningham
Nurse Consultant/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation/Center for Devices and Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Cunningham, Terrell

From: FDA Postmaster for Exchange
nt: Friday, June 13, 2008 1:11 PM
: Cunningham, Terrell
Subject: Delivery Status Notification (Relay)

Attachments: ATT126684.txt; K080795 ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown

(b)(4) [redacted] This is an automatically generated Delivery Status Notification.

Your message has been successfully relayed to the following recipients, but the requested delivery status notifications may not be generated by the destination.

David.Lee@kcc.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-0547, released by CDRH on 03-28-2016

Abbreviated
K080795/S1

Date: May 13, 2008
To: The Record
From: Terrell Cunningham, Nurse Consultant
Office: ODE
Division: DAGID
Device Name: K080795 ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown
Contact: Mr. David Lee
Firm: Kimberly-Clark Corp.
Phone: 770 587-7167
Fax: 920 969-5160
Email: David.Lee@kcc.com

Our review of your 510(k) submission has identified several deficiencies that need to be resolved before we will be able to make a recommendation. To complete the review of this submission, please provide a response to the following:

(b)(4)

[redacted]

PLAN: Please provide this information within 30 days. Effective today, June 13, 2008, your submission has been placed on hold pending receipt of the above additional information. If you have any questions, please contact me by fax at 240-276-3789, phone at 240-276-3766, or by email at terrell.cunningham@fda.hhs.gov.

Cunningham

Terrell Cunningham
Nurse Consultant/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation/Center for Devices and Radiological Health

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-3) NO ANSWER
E-2) BUSY
E-4) NO FACSIMILE CONNECTION

NOTE

2241 MEMORY TX Kimberly-Clark 14 OK 1/1

TRANSMITTED/STORED : JUN. 13. 2008 1:26PM
FILE MODE OPTION ADDRESS RESULT PAG

FAX HEADER 1: FAD-CDRH-ODE-DAGID
FAX HEADER 2:

* * * COMMUNICATION RESULT REPORT (JUN. 13. 2008 1:26PM) * * *

P. 1

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Terrell Cunningham

Subject: 510(k) Number K080795

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: (Branch Chief) (Branch Code) (Date) 5/14/08

Final Review: (Division Director) (Date)

Rev. 5/30/07

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			
3. Does this device type require a PMA by regulation? (Please see management.)			
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			
5. a. Did the firm request expedited review? (See management.)			
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			

Rev. 5/30/07

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Premarket Notification [510(k)] Review
Abbreviated
K080795

Date:	May 13, 2008	
To:	The Record	Office: ODE
From:	Terrell Cunningham, Nurse Consultant	Division: DAGID
Device Name:	K080795 ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown	
Contact:	Mr. David Lee	
Firm:	Kimberly-Clark Corp.	
Phone:	770 587-7167	
Fax:	920 969-5160	
Email:	David.Lee@kcc.com	

I. Purpose and Submission Summary

The 510(k) holder, Kimberly-Clark Corp. has submitted a premarket notification for ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown. The purpose of the submission is to declare nformity of the product to Association for the Advancement of Medical Instrumentation (AAMI) PB70:2003, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or **OTC**)	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Form	√		

STANDARDS REFERENCED:

1. AAMI PB7O, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, 2003
2. ISO 10993-5 , Biological Evaluation of Medical Devices -Part 5: Test for in Vitro and Cytotoxicity
3. ISO 10993-10, Biological Evaluation of Medical Devices -Part 10: Test for Irritation and Delayed-type Hypersensitivity.
4. ANSI/AAMI/ISO 11135-1 Sterilization of Healthcare Products – Ethylene oxide – Part1: Requirements for Development, Validation, and Routine Control of Ethylene Oxide Sterilization
5. "ANSI/AAMI/ISO 10993-7: Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals,"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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III. Device Description

The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown manufactured by Kimberly-Clark Corp. are full-length, (b)(4) [redacted] The ULTRA Fluid Barrier Surgical Gown is film-reinforced ((b)(4) [redacted] for added barrier protection. Graphic designs of the gowns were provided for review. The gowns are available in sizes small, medium, large and extra large. The sponsor claims that the ULTRA Surgical Gown meets the AAMI Level 3 requirements for liquid barrier performance and that the ULTRA Fluid Barrier Surgical Gown meets the AAMI Level 4 requirements for liquid barrier performance. The basic construction of the gowns and the device dimensions are provided for our review in Section 12 of the submission.

Recommendations: (b)(4) [redacted]
(b)(4) [redacted]

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	
Is the device sterile?	√		
Is the device reusable (not reprocessed single use)?		√	
Are "cleaning" instructions included for the end user?			

IV. Indications for Use

The firm states that the indication for use for the device is as follows:
The Kimberly-Clark* ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gown meets Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Fluid Barrier Surgical Gown meets Level 4 of the AAMI Liquid Barrier classifications.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Reviewer Comments: (b)(4) [redacted]

Recommendations: (b)(4) [redacted]

V. Predicate Device Comparison

The sponsor claims that their gowns are substantially equivalent to the predicate Kimberly-Clark KIMGUARD and SPUNGUARD Surgical Gowns in intended use, design, material, and biocompatibility attributes. The sponsor also claims that the performance attributes of the ULTRA gowns are substantially equivalent to the predicate gowns with the exception that the ULTRA Surgical Gown meets the requirements of AAMI Level 3 liquid barrier requirements and the ULTRA Fluid Barrier Surgical Gown meets the requirements of AAMI Level 4 liquid barrier requirements. The ULTRA surgical gowns and their predicates are provided sterile, single use. The referenced predicates have been previously cleared for market and was the subject of K781682 (Kimberly-Clark KIMGUARD Surgical Gowns and Drapes) and K842115 (Kimberly-Clark SPUNGUARD Surgical Drapes, Gowns and Packs). K781682 and K842115 are not available for review on IMAGE.

Recommendations: (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted]

VI. Labeling

Draft copies of labeling were provided for our review. The labeling provided for our review includes the following claims/statements:

The labeling for the ULTRA and ULTRA Fluid Barrier Surgical Gown provided for our review contains the following information:

- Manufacturer name and address
- Contents of the package (…Polypropylene Fabric/ with Film-Reinforced)
- Size
- Lot number
- Sterile-EO
- Single-Use
- Disposable
- Expiration Date
- AAMI Level 3/ AAMI Level 4
- Natural Rubber Latex Free
- With Towel

(b)(4) [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4)

(b)(4)

VII. Sterilization/Shelf Life/Reuse

The Ultra Surgical Gowns are sterilized by ethylene oxide (EQ) with a Sterility Assurance Level (SAL) of 10-6. The ethylene oxide sterilization of the surgical gowns was validated according to ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices. Ethylene oxide residuals were validated as being within the acceptance criteria according to ANSI/AAMI/ISQ 10993-7:1995 Biological evaluation of medical devices, Part 7: Ethylene oxide sterilization residuals, Section 4.3.3 Limited Exposure Devices, as summarized in the table below.

Summary of EO Residuals Validation

EO Residual	Acceptance Criteria	ULTRA Surgical Gowns	ULTRA Fluid Barrier Surgical Gowns

(b)(4)

The firm states that ULTRA Surgical Gowns are provided in a (b)(4) (b)(4).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Sterilization Checklist

1. Sterilant:	YES	NO
a. Sterilization method description (e.g., Steam, ***EO,*** Radiation):	X	
b. Dose, for radiation (e.g., 25 – 50 kGy):	N/A	
c. Sterilant residuals remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	X	
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended (e.g., ANSI/AAMI/ISO 11135))	ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products –Ethylene oxide-Part 1: Requirements for development, validation , and routine control of a sterilization process for medical devices.	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	X	
4. Is it labeled "Pyrogen Free"?		X
If so, a description of the method: (e.g., LAL (Limulus Amebocyte Lysate test))	N/A	
5. A description of the packaging (not including package integrity test data):	X	

(b)(4)

[redacted]

VIII. Biocompatibility

Refer to section XII Performance Testing – Animal, below.

IX. Software

Not applicable

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable

XI. Performance Testing – Bench

The firm claims that the Ultra Surgical Gowns have been evaluated in accordance with the test requirements for surgical gowns in AAMI PB70:2003.

Physical Attributes

Attributes	Reference Standard	ULTRA Surgical Gowns (AAMI Fluid Barrier Level 3)	ULTRA Fluid Barrier Surgical Gowns (AAMI Fluid Barrier Level 4)
Basis Weight	ASTM[1] D3776 -07 Standard Test Methods for Mass Per Unit Area (Weight) of Fabric	(b)(4) [redacted] (ounces per square yard)	
Resistance to blood and liquid penetration	• ANSI/AAMI PB70:2003 *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* • AATCC 42:2000 *Water resistance: Impact penetration test* • AATCC 127:1998 *Water resistance: Hydrostatic pressure test*	The entire front of the gown (critical zones A, B, and C) must meet the following at AQL 4.0: Pass Spray Impact ≤ 1.0 g Pass Hydrostatic Head ≥ 50 cm	Not applicable
	• ANSI/AAMI PB70:2003 *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* • ASTM F1671:2003	Not applicable	The entire front of the gown (critical zones A, B, and C) must meet the following at AQL 4.0: Pass ASTM F 1671

The sponsor claims that performance data demonstrating an AQL of 4%:

- The ULTRA Surgical Gown has been tested in compliance with the requirements of Level 3 liquid barrier performance requirements of ANSI/AAMI PB7O: 2003

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

"Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities."

- The ULTRA Fluid Barrier Surgical Gown has been tested in compliance with the requirements of Level 4 liquid barrier performance requirements of ANSI/AAMI PB7O: 2003.

The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown also meet the requirements of the National Fire Protection Association (NFPA) Test Method 702-1980 for Class I.

Mechanical Design Attributes

Attributes	Reference Standard	ULTRA Surgical Gowns (AAMI Fluid Barrier Level 3)	ULTRA Fluid Barrier Surgical Gowns (AAMI Fluid Barrier Level 4)
Grab Tensile Strength, CD/MD[2]	ASTM D 5034-95 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	(b)(4)	
Static Dissipation	INDA[3] Standard Test Methods IST 40.2-01 Electrostatic Decay of Nonwoven Fabrics	≤ (b) seconds	
Flame Resistance of NonWoven Fabrics (30 second burn challenge)	NFPA[4] 702-1980, specifications for fabrics without raised-fiber surfaces.	≥ (b) second flame spread time (Corresponds to the acceptance criteria of NFPA 702-1980 for Class 1, slow burning fabrics with a flame spread time of 20 seconds or more)	
Linting	INDA Standard Test Methods IST 160.1-01 Resistance to Linting of Nonwoven Fabric (Dry)	≤ (b)(4), 10.0 micron in diameter	≤ (b) particles, 10.0 micron in diameter

Conclusion: The performance testing data summaries provided are adequate.

XII. Performance Testing – Animal

The ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown were tested in accordance with the biocompatibility requirements of ISO 10993 for surface devices with limited contact with breached or compromised surfaces. The firm states that the final finished sterilized gowns were tested. Copies of the actual test results were provide for our review. All biocompatibility test results are acceptable as summarized in the tables below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Table 16-1. Biocompatibility Results for ULTRA Surgical Gown

Test Type	Ref Standard Described in Report	Acceptance Criteria	Test Result	Test Report Identification
(b)(4) [redacted]				

Table 15-2. Biocompatibility Results for ULTRA Fluid Barrier Surgical Gown

Test Type	Ref Standard Described in Report	Acceptance Criteria	Test Result	Test Report Identification
(b)(4) [redacted]				

XIII. **Performance Testing – Clinical**: None provided. Not needed to determine substantial equivalence.

XI. Substantial Equivalence Discussion

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Yes	No	
1. Same Indication Statement?	√		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	√		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		√	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?		√	**If NO = Request Data**
9. Data Demonstrate Equivalence?			Final Decision:

Note: Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed: Performance test data/ revised declaration of conformity is needed to demonstrates that the device is or is not substantially equivalent to the predicate device.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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X. Deficiencies

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Deficiencies

[redacted]

XII. Recommendation: Recommend that K080795 ULTRA Surgical Gowns and ULTRA Fluid Barrier Surgical Gowns be placed on HOLD pending receipt of response from firm to our request for additional information.

Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA

Terrell A. Cunningham
Reviewer

May 13, 2008
Date

Dr. Sheila Murphey

5/14/08

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

DHHS/PHS/FDA/CDRH
DIVISON OF ANESTHESIOLOGY, GENERAL HOSPITAL, INFECTION CONTROL AND DENTAL DEVICES
CORPORATE BOULEVARD, HFZ-480
ROCKVILLE, MARYLAND 20850

FROM: TERRELL A. CUNNINGHAM

DATE: May 14, 2008

NO. OF PAGES: 3

PHONE NUMBER: (240) 276-3766
FAX NO: (240) 276-3789
E-MAIL ADDRESS: terrell.cunningham@fda.hhs.gov

Subject :	K080795
Contact:	Mr. David Lee
Firm:	Kimberly-Clark Corp.
Phone:	770 587-7167
Fax:	920 969-5160
Email:	David.Lee@kcc.com

ADDITIONAL COMMENTS: Please see attachment.

Please provide this information within 30 days. Your document has been placed on hold pending receipt of the above additional information. If you have any questions, please contact me by fax at 240-276-3789, phone at 240-276-3766, or by email at terrell.cunningham@fda.hhs.gov.

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

MEMORANDUM

Date:	May 13, 2008	
To:	The Record	Office: ODE
From:	Terrell Cunningham, Nurse Consultant	Division: DAGID
Device Name:	K080795 ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown	
Contact:	Mr. David Lee	
Firm:	Kimberly-Clark Corp.	
Phone:	770 587-7167	
Fax:	920 969-5160	
Email:	David.Lee@kcc.com	

Our review of your 510(k) submission has identified the following deficiency that need to be resolved before we will be able to make a recommendation. To complete the review of this submission, the sponsor will be asked to provide a response to the following:

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]

Recommendation: Recommend that K080795 ULTRA Surgical Gowns and ULTRA Fluid Barrier Surgical Gowns be placed on HOLD pending receipt of response from firm to our request for additional information.

If you have any questions concerning the contents of the letter, please contact Terrell Cunningham at (240) 276-3766 or by email at terrell.cunningham@fda.hhs.gov.

If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Terrell Cunningham
Nurse Consultant/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
(301) 443-8913 X146
(301) 480-3002 Fax
terrell.cunningham@fda.hhs.gov

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

* * * COMMUNICATION RESULT REPORT (MAY. 14. 2008 3:12PM) * * *

FAX HEADER 1: FAD-CDRH-ODE-DAGID
FAX HEADER 2:

TR MITTED/STORED : MAY. 14. 2008 3:11PM

F	ODE	OPTION	ADDRESS	RESULT	PAGE
214	MEMORY TX		Kimberly-Clark 14	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DHHS/PHS/FDA/CDRH
DIVISON OF ANESTHESIOLOGY, GENERAL HOSPITAL,
INFECTION CONTROL AND DENTAL DEVICES
CORPORATE BOULEVARD, HFZ-480
ROCKVILLE, MARYLAND 20850

FROM: TERRELL A. CUNNINGHAM

DATE: May 14, 2008

NO. OF PAGES: 3

PHONE NUMBER: (240) 276-3766
FAX NO: (240) 276-3789
E-MAIL ADDRESS: terrell.cunningham@fda.hhs.gov

Subject :	K080795
Contact:	Mr. David Lee
Firm:	Kimberly-Clark Corp.
Phone:	770 587-7167
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Email:	David.Lee@kcc.com

ADDITIONAL COMMENTS: Please see attachment.

Please provide this information within 30 days. Your document has been placed on hold pending receipt of the above additional information. If you have any questions, please contact me by fax at 240-276-3789, phone at 240-276-3766, or by email at terrell.cunningham@fda.hhs.gov.

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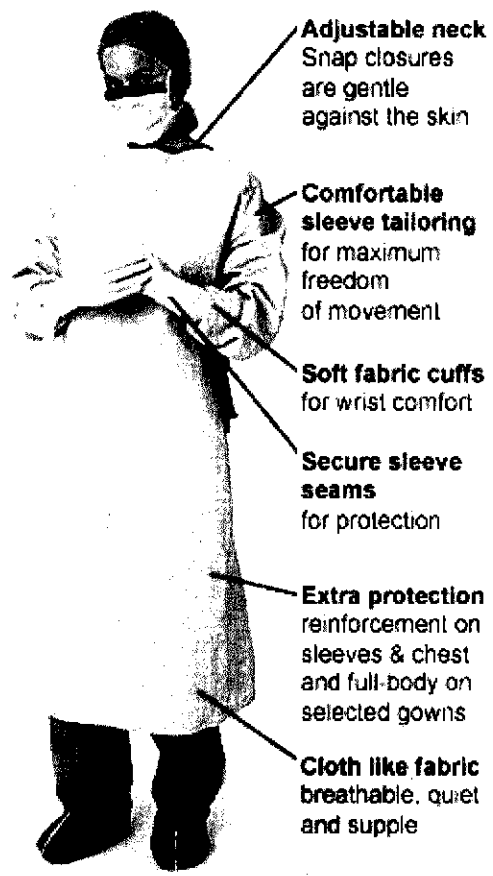
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647, Released by CDRH on 03-28-2016

Surgical gowns

Kimberly-Clark® surgical gowns

Provide exceptional barrier protection with the comfort you need.



Our surgical gowns are manufactured from polypropylene, a non-woven fabric with the benefits of low linting, ignition resistance and protection from airborne and blood borne bacteria.

Our range of gowns allows you to tailor the appropriate level of protection according to the level of exposure to blood and body fluids that is anticipated with the surgical procedure.

It is up to the Operating Room staff to select the appropriate gown to meet the desired level of protection and this is generally based on trial and in-use experience.

The guide below provides a starting point for identifying the optimum gown selection for your Operating Room.

- **Light to moderate exposure**: Evolution* 4 or Ultra surgical gowns
- **Moderate to High**: Evolution* 4, Ultra surgical gown; Ultra fabric reinforced
- **Extended procedures with High exposure**: Ultra Zoned Impervious†, Ultra Impervious† or MicroCool® Breathable Impervious† surgical gowns.

  Kimberly-Clark surgical gowns are designed to remain comfortable throughout the procedure. The fabric is light and breathable.

  For surgical procedures requiring impervious protection, Kimberly-Clark has introduced the MicroCool® gown which incorporates a breathable impervious film to permit evaporation of sweat and filters out bacteria to a particle size smaller than Hepatitis C.

  The gowns are generously cut to allow a range of movement around the shoulders and our impervious gowns are also offered in the "A" line style to so they remain comfortable when used by surgeons operating whilst seated.

  The neck closure system offers two or three adjustments depending on the style and uses easy snap closures that are gentle against the skin.

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Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or 301-796-8118

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In the interest of electrical safety, all our gowns have anti static properties so they remain static dissipative throughout their lifespan.

MicroCool® gowns use our advanced microporous fabric technology to ensure breathable comfort and impervious protection. Please see our technology section for more details

Our selection of surgical gowns is available in the single sterile presentation and they can be included in a range of Kimberly-Clark sterile packs. The full gown selection is also available in the bulk non-sterile format for inclusion in custom procedure trays.

Kimberly-Clark is pleased to work closely with a custom procedure tray manufacture of your choice to ensure inclusion of your preferred gown selection in each pack. All of our customers are included in the Customer Care Program to ensure our high standard of service is provided on an ongoing basis.

Our dedicated Custom Procedure Tray Manager maintains a business partnership with the custom procedure tray supplier of your choice to ensure you receive continued access to Kimberly-Clark Customer Care Programs.

Ordering information

These products are available from a wide range of distributors.

To order please call **1800 810 077**.

For more information regarding our products call our *Customer Care* line **1800 101 021**.

† The barrier properties of the gown may be breached if it is abraded, stretched or punctured by a sharp object.

The products listed in this directory have been introduced specifically for healthcare providers in Australia and New Zealand. Additional information is available on the United States based Kimberly-Clark Health Care website.

Kimberly-Clark makes no representation that its products described in this website will provide complete protection from exposure to contaminants, fluids, or micro organisms or will eliminate the risk of contracting infectious diseases.

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Questions? Contact FDA/CDRH/OCE/DIDsat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Show Checkout items only **Showing all items** Show grid view Sort by relevance

Kimberly Clark Gown Ultra Non-reinforced X-large 30/ca - Model 95121
Features: **Kimberly Clark Gown** Ultra Non-Reinforced X-Large 30/Ca - Model 95121 Categorization: Surgical Accessories > Miscellaneous Product ...
Add to Shopping List

$256.51
eGeneralMedical.com ...
★★★★☆ 392 seller ratings

Kimberly-clark Evolution* 4 Surgical **Gowns** Large
Features: **Kimberly-Clark** Evolution* 4 Surgical **Gowns** Large * Large * Each * Model # 90018 Product Information:**Kimberly-Clark** Evolution* 4 Surgical **Gowns** ...
Add to Shopping List

$15.00
eGeneralMedical.com ...
★★★★☆ 392 seller ratings

Kimberly-clark Ultra Surgical **Gowns** Large
Features: **Kimberly-Clark** ULTRA Surgical **Gowns** Large * Large * Case/32 * Model # 95111 Product Information:**Kimberly-Clark** ULTRA Surgical **Gowns** Large ...
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$228.60
eGeneralMedical.com ...
★★★★☆ 392 seller ratings

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Own Canadian Vacation Property
Located In Kimberley BC.
www.northstarmountainvillage.com

Kimberly Clark Products
Kimberly Clark Paper, Dispensers & More - Compare our prices!
www.PSJanitorial.com

Dresses
Shop Women's Dresses - Many Styles and Occasions at MSNshopping.com!
Shopping.MSN.com

Gowns
Find **Gowns** Online.
Shop & Save at Target.com Today.
www.Target.com

Clarks
Free Shipping both ways on Clarks Shoes. 365 Day Return Policy
www.zappos.com

Dresses
Shop by brand, shape or occasion
Free Shipping on Orders over $200!
www.nordstrom.com

Locate This Person
Current address and phone available. Search free.
www.usa-people-search.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

HHO

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Kimberly-clark Ultra Surgical **Gowns** Small
Features: **Kimberly-Clark** ULTRA Surgical **Gowns** Small * Small * Each * Model # 95101 Product Information:**Kimberly-Clark** ULTRA Surgical **Gowns** Small ...
Add to Shopping List

$17.67
eGeneralMedical.com ...
★★★★☆ 392 seller ratings

Kimberly-clark Procedure **Gown** Large
Features: **Kimberly-Clark** Procedure **Gown** Large * Large * Case/60 * Model # 69025 Product Information:**Kimberly-Clark** Procedure **Gown** Large : Protective, ...
Add to Shopping List

$260.89
eGeneralMedical.com ...
★★★★☆ 392 seller ratings

Kimberly-clark Impervious **Gown**
Features: **Kimberly-Clark** Impervious **Gown** * Case/100 * Model # 69600 Product Information:**Kimberly-Clark** Impervious **Gown** : Provides protection from heavy ...
Add to Shopping List

$283.12
eGeneralMedical.com ...
★★★★☆ 392 seller ratings

Kimberly-clark Procedure **Gown** Extra-large
Features: **Kimberly-Clark** Procedure **Gown** Extra-Large * Extra-Large * Case/60 * Model # 69026 Product Information:**Kimberly-Clark** Procedure **Gown** Extra-Large ...
Add to Shopping List

$260.89
eGeneralMedical.com ...
★★★★☆ 392 seller ratings

Kimberly Clark Ultra Surgical **Gown** With Towel,

$252.97
MedexSupply.com
★★★★☆ 80 seller ratings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Small
Kimberly Clark Ultra Surgical **Gown** With Towel. Size Small. Sterile. 34 GownsCase.
Add to Shopping List -
Google Checkout

Kimberly-clark Evolution* 4 Surgical **Gowns** Large
* **Kimberly-Clark** Evolution* 4 Surgical **Gowns** Large * * Large * * Each * Model # 90018 **Kimberly-Clark** Evolution* 4 Surgical **Gowns** Large : Features:Evolution ...
Add to Shopping List

$15.00
eGeneralMedical.com ...
★★★★☆ 392 seller ratings

Kimberly-clark Ultra Surgical **Gowns** Small
* **Kimberly-Clark** ULTRA Surgical **Gowns** Small * * Small * * Each * Model # 95101 **Kimberly-Clark** ULTRA Surgical **Gowns** Small : Features:Proproprietary 4th ...
Add to Shopping List

$17.67
eGeneralMedical.com ...
★★★★☆ 392 seller ratings

Refine product results for: **kimberly-Clark gowns**

Price range	Stores	Seller rating
Under $90	Yhst-22804368657135	4 stars and up
$90 - $200	New England Safety L...	3 stars and up
$200 - $250	eGeneralMedical.com ...	2 stars and up
Over $250	eGeneralMedical.com ...	Has a rating
$ to $ Go	MedMerchant	More »
	More »	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 03, 2008

KIMBERLY-CLARK CORP.
1400 HOLCOMB BRIDGE RD.
BLDG 300, #1092
ROSWELL, GA 30076
ATTN: DAVID M. LEE

510(k) Number: K080795
Product: ULTRA SURGICAL GOWN & FLUID BARRIER SURGICAL GOWN

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 08-28-2016

K080795/S1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
5/30/2008	not applicable, additional information related to 510(k) submitted under [redacted]	K080795

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Kimberly-Clark Corporation	Establishment Registration Number *(if known)* 1033422
Division Name *(if applicable)*	Phone Number *(including area code)* (770) 587 7167
Street Address 1400 Holcomb Bridge Road Building 300, #1092	FAX Number *(including area code)* (920) 225 4784
City Roswell	State / Province: GA; ZIP/Postal Code: 30076-2199; Country: USA
Contact Name David M. Lee	
Contact Title Associate Director of Regulatory Affairs	Contact E-mail Address David.Lee@kcc.com

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name	
Division Name *(if applicable)*	Phone Number *(including area code)* ( )
Street Address	FAX Number *(including area code)* ( )
City	State / Province; ZIP/Postal Code; Country
Contact Name	
Contact Title	Contact E-mail Address

K23 341

PSC Graphics: (301) 443-2434 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Sterilization
  - [ ] Packaging
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Response to FDA correspondence:

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Repose to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:
  This is additional information for 510(k) review K080795. The date of the original 510(k) submission was 3/17/08.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FYA	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

ormation on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K781682	1	KIMGUARD* Surgical Gowns and Drapes	1	Kimberly-Clark*
2	K842115	2	SPUNGUARD Surgical Gowns and Drapes	2	Kimberly-Clark*
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

surgical gown

	Trade or Proprietary or Model Name for This Device		Model Number
1	ULTRA Surgical Gown	1	not applicable
2	ULTRA Film-Reinforced Surgical Gown	2	not applicable
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K781682	2 K842115	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
FYA	878.4040	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

General & Plastic Surgery

Indications *(from labeling)*

The Kimberly-Clark* ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address		

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address		

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Kimberly-Clark
Request # 2015-9647; Released by CDRH on 03-28-2016

May 30, 2008

Terrell Cunningham
Nurse Consultant/Reviewer
FDA/CDRH/ODE/DAGID/ICDB
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850
(240) 276-3766
(301) 480-3002 Fax
terrell.cunningham@fda.hhs.gov

FDA CDRH DMC
JUN 2 2008
Received

Re: K080795 ULTRA Surgical Gown and ULTRA Fluid Barrier Surgical Gown

Dear Mr. Cunningham,

Kimberly-Clark received on May 14 the list of deficiencies in your May 13, 2008 Memorandum that need to be resolved before you can make a substantial equivalence recommendation for the referenced 510(k) review. Please note that the surgical gowns subject to this 510(k) submission are currently marketed under K842115 (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) Deficiencies [redacted]

367

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Please contact me if I can be of further assistance.

Sincerely,

David M. Lee
Associate Director of Regulatory Affairs
Phone: 770 587 7167
FAX: 920 225 4784
David.Lee@kcc.com

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attachment 1

Labeling provided for the surgical gowns in 510(k) submissions
K781682 and K842115

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

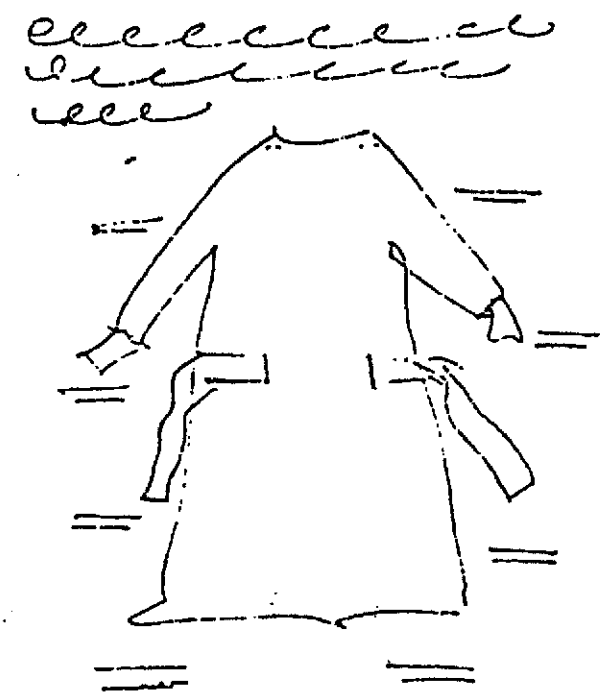
Labeling in K781682

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Psssst! Finally,
A Disposable Gown
Your Surgeons
will wear. Psssss
ssss ssss ssss
sssssssssss
sssssssss
ssssssssss
ssst! It's Not Paper.

New KIMGUARD™ Surgical Gown



Commitment Plan

Fabric Sample

Psssssssssst!
It's Not Paper.

EXHIBIT A

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6/27/78

APPROVAL	
NAME	DATE

Job No: 1508

Project: New KIMGUARD Gown Collateral

COPY

COVER

Pssssst! Finally, A Disposable Gown Your Surgeons Will Wear. Pssssssssssssssssst!

It's Not Paper.

INSIDE

New KIMGUARD(TM) Surgical Gown

Special 'breathable' non-woven fabric eliminates many of the undesirable characteristics associated with disposable gowns.

CAPTIONS

Soft, like cloth - eliminates stiffness and rustling.

Breathable - more comfort, less heat build-up during long procedures.

Lightweight - only 1/3 the weight of muslin gowns.

Seamless - special ultra-sonic construction eliminates needle holes, and needle hole fluid 'strike-through'.

Improved Bacterial Barrier - sterile covering for your surgical team, plus outstanding filter medium to contain shed skin particles and retard bacterial migration.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

1508/2

Fluid Repellent - to reduce risk of cross-contamination resulting from fluid 'strike-through'.

Extremely Low Lint - depending on particle size, some muslin gowns have up to 100 times more lint.

Tough Cuff - material is strong to help eliminate gown cuff tearing away from gown or accidental tear holes in sleeve when surgeon adjusts cuff and gloves.

Eliminates Time-Consuming, Costly Processing - Disposabliity eliminates laundering, inspecting, delinting, patching, folding, wrapping and sterilizing.

INSERT FLAP

Psssssssssssssst! It's Not Paper .

(KC)

Kimberly-Clark Corporation

Hospital Products

BACK

Form No _____

Kimguard is a Trademark of Kimberly-Clark Corp., Neenah, WI 54956 (C) 1978 All Rights Reserved. Printed in U.S.A.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Kimguard™ Surgical Gowns

Health-Care Products
Kimberly-Clark Corporation

Contents sterile unless this package is opened or damag
Remove outside film dust co
prior to use near hazardous atmosphere

One **Medium** overlap back style surgical gown
Reorder No. 10400

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

STERILE SINGLE-PATIENT PRODUCTS FOR SURGERY

Stock Number	SM I SURGICAL GOWNS	Gowns Per Case	Case Weight	CASE PRICE 750	500	250	100	50	10
	FULL OVERLAP BACK STYLE COMFORTAB® Closure								
67130	Medium, 1 Gown per pkg.	24	18 lbs.	$52.35	$53.40	$54.45	$55.50	$57.05	$61.25
67140	Large, 1 Gown per pkg.	24	19 lbs.	55.30	56.40	57.50	58.60	60.25	64.70
69000	Large, 2 Gowns per pkg.	24	16 lbs.	52.85	53.90	55.00	56.05	57.60	61.35
67132	Medium, 1 Gown per pkg. w/protective panels	24	20 lbs.	57.05	58.20	59.35	60.50	62.20	66.75
67142	Large, 1 Gown per pkg. w/protective panels	24	21 lbs.	59.95	61.15	62.35	63.55	65.35	70.15
	STANDARD OVERLAP BACK STYLE								
69270	Medium, 1 Gown per pkg.	24	18 lbs.	46.80	47.75	48.65	49.60	51.00	54.75
69280	Large, 1 Gown per pkg.	24	18.5 lbs.	51.30	52.35	53.40	54.40	55.95	60.05
69290	Large, 2 Gowns per pkg.	24	18 lbs.	48.90	49.85	50.85	51.80	53.30	57.20

Stock Number	SM II SURGICAL GOWNS	Gowns Per Case	Case Weight	CASE PRICE 750	500	250	100	50	10
	FULL OVERLAP BACK STYLE COMFORTAB® Closu								
69050	Medium, 1 Gown per pkg.	24	18 lbs.	$65.75	$67.05	$68.35	$69.65	$71.65	$76.90
69060	Large, 1 Gown per pkg.	24	19 lbs.	67.20	68.55	69.90	71.25	73.25	[illegible]
69070	Large, 2 Gowns per pkg.	24	16 lbs.	65.90	67.20	68.55	69.85	71.85	77.10
69061	Large, 1 Gown per pkg. w/protective panels	24	21 lbs.	74.60	76.10	77.60	79.10	81.33	87.30

78.65

Stock Number	COMPONENTS	Items Per Pkg.	Items Per Ca.	Case Weight	CASE PRICE 750	500	250	100	50	10
67620	Small Drape Sheet 15"x30"	2	50	4 lbs.	$14.65	$14.95	$15.25	$15.55	$16.00	$17.15
67300	Regular Drape Sheet 48"x60"	1	25	8 lbs.	24.35	24.85	25.35	25.80	26.65	28.50
67700	Large Drape Sheet 60"x78"	1	25	13 lbs.	41.35	42.20	43.00	43.85	45.10	48.40
69120	Small Fenestrated Sheet 30"x30"	1	25	9 lbs.	30.65	31.25	31.85	32.50	33.40	35.85
67650	Small Split Sheet 60"x78"	1	25	14 lbs.	63.75	65.05	66.30	67.60	69.50	74.60
67550	Large Split Sheet 78"x120"	1	10	14 lbs.	44.35	45.25	46.15	47.00	48.35	51.90
67530	Winged Laparotomy Sheet 106"x120"	1	10	16.5 lbs.	51.30	52.30	53.35	54.35	55.90	60.00
67540	Ear Sheet 48"x100"	1	10	10 lbs.	29.35	29.95	30.55	31.10	32.00	34.35
67620	Laparotomy Sheet 78"x120"	1	10	14 lbs.	44.35	45.25	46.15	47.00	48.35	51.90
67560	Transverse Lap Sheet 78"x120"	1	10	14 lbs.	45.20	46.10	47.00	47.95	49.20	52.90
67600	Pediatric Lap Sheet 60"x108"	1	10	9 lbs.	32.90	33.55	34.20	34.90	35.85	38.50
67590	Under Buttock Drape 40"x44"	1	25	13 lbs.	26.65	27.20	27.75	28.25	29.05	31.20
69100	Orthopedic Sheet 60"x78"	1	10	14 lbs.	25.40	25.90	26.45	26.95	27.70	29.75
69110	Thyroid Sheet 78"x120"	1	10	19 lbs.	44.35	45.25	46.15	47.00	48.35	51.90
67060	Legging 24"x40"	1	25	10 lbs.	28.00	28.55	29.10	29.65	30.50	32.75
67010	Absorbent Towel 15"x30"	5	125	9 lbs.	19.85	20.25	20.60	21.00	21.60	23.20
67030	Table Cover 45"x78"	1	25	10 lbs.	27.80	28.35	28.90	29.45	30.30	32.50
67670	Mayo Stand Cover 25"x54"	1	25	11 lbs.	29.05	29.65	30.20	30.80	31.65	34.00
69150	Chest Sheet 78"x120"	1	10	14 lbs.	52.40	53.45	54.50	55.55	57.10	61.30
69160	Knee Sheet 78"x120"	1	10	14 lbs.	51.90	52.95	54.00	55.05	56.60	60.75
69170	U Sheet 78"x100"	1	10	12 lbs.	54.20	55.25	56.35	57.45	59.05	63.40
69180	Orthopedic Stocking	1	10	6.4 lbs.	26.65	27.20	27.75	28.25	29.05	31.20

* AVAILABLE 1/5/4

95 [illegible] 11/25. [illegible]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Labeling in K842115

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SURGICAL PRODUCTS—STERILE

Stock Number	SPUNGUARD® SURGICAL PACKS	Packs Per Case	Cube
88731	**CARDIOVASCULAR PACK** 1 Back Table Cover, Reinforced 90" x 44" 1 Surgical Gown, Large (90112) with Hand Towel in Overwrap 2 Hand Towels 30" x 15" 2 Surgical Gowns, Large (90112) 1 Mayo Stand Cover, Reinforced 23½" x 55" 1 Operating Table Cover 60" x 77" • ISO-SEAL® Positioning Tape • CONTROL® Fabric Reinforcement 3 Absorbent Towels 30" x 15" 2 Sterile Foot Covers 1 Perineum Cover • ISO-SEAL® Positioning Tape 1 Umbilicus Cover 30" x 15" 6 Utility Drapes 30" x 15" • ISO-SEAL® Positioning Tape 1 Suture Bag 1 Cardiovascular Sheet 90" x 110" with Anesthesia Screen 120" and 4" x 92" Split • ISO-SEAL® Positioning Tape • CONTROL® Fabric Reinforcement • Built-in Perfusion Pump Tubing Pockets 1 Large Drape 60" x 77"	2	1.72
88811	**OB PACK I** 1 Back Table Cover, Reinforced 78" x 44" 1 Set-Up Cover 77" x 44" 2 Absorbent Towels 30" x 15" 1 Under Buttocks Drape 38½" x 44" • Poly Reinforcement 2 Leggings 30" x 37" 1 Abdominal Drape 38½" x 60" • ISO-SEAL® Positioning Tape • CONTROL® Fabric Reinforcement	8	1.72
88821	**OB PACK II** 1 Back Table Cover, Reinforced 78" x 44" 1 Set-Up Cover 77" x 44" 2 Absorbent Towels 30" x 15" 1 Under Buttocks Drape 38½" x 44" • Poly Reinforcement 2 Leggings 30" x 37" 1 Abdominal Drape 38½" x 60" • ISO-SEAL® Positioning Tape • CONTROL® Fabric Reinforcement 1 Vaginal Packing Sponge 2 Peri Pads 1 Hollister® Cord Clamp 1 Placenta Basin	5	1.72
88831	**OB PACK III** 1 Back Table Cover, Reinforced 78" x 44" 1 Set-Up Cover 77" x 44" 1 Hand Towel 30" x 15" 1 Surgical Gown, Large/Tie-Back (90212) 2 Absorbent Towels 30" x 15" 1 Baby Blanket 26" x 30" 1 Under Buttocks Drape 38½" x 44" • Poly Reinforcement 2 Leggings 30" x 37" 1 Abdominal Drape 60" x 35½" • ISO-SEAL® Positioning Tape • CONTROL® Fabric Reinforcement 1 Vaginal Packing Sponge 2 Peri Pads 1 Hollister® Cord Clamp 1 Bulb Syringe 1 Placenta Basin	5	2.01

Stock Number	SPUNGUARD® SURGICAL GOWNS		Items Per Package	Items Per Case	Cube
90102	SMALL	Sterile-Back with Hand Towel(s)	1	32	2.01
90112	LARGE		1	32	2.01
90122	LARGE		2	32	2.01
90132	LARGE		3	33	2.01
90142	X-LARGE		1	30	2.01
90212	LARGE	Tie-Back with Hand Towel	1	34	2.01
90312	LARGE	Sterile Back with Impervious Reinforcements and Hand Towel	1	32	2.01
90342	X-LARGE		1	30	2.01
90412	LARGE	Sterile-Back Specialty/ Impervious with Hand Towel	1	24	2.01
90442	X-LARGE		1	22	2.01

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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ATTACHMENT B (Continued)

90720

Surgical Gown

1 Surgical Gown
Sterile Back/Small
☐ 1 Absorbent Towel
☐ 1 CSR Wrap, 25" x 25"

Contents Sterile
Unless This Package Is Opened Or Damaged.
Single-Use Product. Do Not Reuse.

Kimberly-Clark Corporation
Health Care Products Group
Roswell, GA 30076

Assembled in Mexico of U.S.-made materials.

CONTROL NO.

SURGIDAY SYSTEM IS A TRADEMARK OF KIMBERLY-CLARK CORPORATION.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attachment 2

Dimensional Drawings for the following gowns:

Ultra Surgical Gowns AAMI Level 3:

- 95101 ULTRA Surgical Gown, Small
- 95111 ULTRA Surgical Gown, Large
- 95121 ULTRA Surgical Gown, X-Large
- 95055 ULTRA Surgical Gown, Large (2 Pack)
- 95131 ULTRA Surgical Gown, XX-Large

Ultra Film-Reinforced Surgical Gown AAMI Level 4: *

- 95411 ULTRA Film-Reinforced Surgical Gown, Large
- 95421 ULTRA Film-Reinforced Surgical Gown, X-Large
- 95431 ULTRA Film-Reinforced Surgical Gown, XX-Large
- 95511 ULTRA Film-Reinforced Specialty Surgical Gown, Large
- 95521 ULTRA Film-Reinforced Specialty Surgical Gown, X-Large
- 95531 ULTRA Film-Reinforced Specialty Surgical Gown, XX-Large

* Note that the film reinforced gown drawings are labeled as "impervious" gowns, though that term is used only internally due to historical use of the name, and will not be used in the labeling on marketed product.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-6617; Released by CDRH on 03-28-2016

(b)(4) Drawings

[redacted]

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Drawings

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-6617; Released by CDRH on 03-28-2016

(b)(4) Drawings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Drawings

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Drawings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Drawings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Drawings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Drawings

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Drawings

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Drawings

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Drawings

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attachment 3

Revised Indications for Use Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Indications for Use

510(k) Number (if known): _____

Device Name: ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns

Indications for Use:

The Kimberly-Clark* ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Addendum:

The ULTRA Surgical Gowns AAMI Level 3 are available under the following Reference Numbers:

- 95101 ULTRA Surgical Gown, Small
- 95111 ULTRA Surgical Gown, Large
- 95121 ULTRA Surgical Gown, X-Large
- 95055 ULTRA Surgical Gown, Large (2 Pack)
- 95131 ULTRA Surgical Gown, XX-Large

The ULTRA Film-Reinforced Surgical Gowns AAMI Level 4 are available under the following Reference Numbers:

- 95411 ULTRA Film-Reinforced Surgical Gown, Large
- 95421 ULTRA Film-Reinforced Surgical Gown, X-Large
- 95431 ULTRA Film-Reinforced Surgical Gown, XX-Large
- 95511 ULTRA Film-Reinforced Specialty Surgical Gown, Large
- 95521 ULTRA Film-Reinforced Specialty Surgical Gown, X-Large
- 95531 ULTRA Film-Reinforced Specialty Surgical Gown, XX-Large

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attachment 4

Labeling of the Devices Subject of this 510(k) Submission

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

The Contents Statement that is Placed on Every Gown Package

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(ER) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) STERIL, solange die Packung nicht geöffnet oder beschädigt ist. VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.
(BG) СЪДЪРЖАНИЕТО Е СТЕРИЛНО ако опаковката не е отворена или повредена. ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.
(ES) CONTENIDO ESTÉRIL, a no ser que este paquete esté abierto o dañado. PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.
(CS) OBSAH JE STERILNÍ, pokud se balení neotevře nebo nepoškodí. POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.
(DA) INDHOLDET ER STERILT med mindre pakken er åbnet eller beskadiget. ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.
(ET) STERIILNE välja arvatud juhul, kui pakend on avatud või kahjustatud. ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.
(EL) ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ: Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.
(IT) CONTENUTO STERILE. Verificare che la confezione sia integra prima dell'uso. AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.
(LV) STERILS SASTĀVS. Izņemot, ja iepakojums atvērts vai bojāts. PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.
(LT) PAKUOTĖS TURINYS STERILUS, kol ši pakuotė neatidaryta ar nepažeista. ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.
(HU) A TARTALMA STERIL kivéve, ha a csomag fel van nyitva vagy sérült. VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.
(NL) INHOUD STERIEL. Tenzij de verpakking open of beschadigd is. OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.
(NO) STERILT INNHOLD. Sterile med mindre pakken er åpnet eller skadet. OBSI Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.
(PL) MATERIAŁ WYJAŁOWIONY. O ile opakowanie nie zostało otwarte lub uszkodzone. PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.
(PT) CONTEÚDO ESTERILIZADO. Verificar a integridade do protector individual de esterilidade antes de usar. ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.
(RO) Acest pachet are un CONȚINUT STERIL dacă nu a fost deschis sau avariat. AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anestezicelor inflamabile. Produsul nu conține latex din cauciuc natural.
(RU) СОДЕРЖИМОЕ СТЕРИЛЬНО, если упаковка не открыта или повреждена. ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика . Не содержит латекса натуральной резины.
(SK) OBSAH JE STERILNÝ, ak sa balenie neotvorí alebo nepoškodí. POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.
(SI) VSEBINA STERILNA. Razen v primeru, da je paket odprt ali poškodovan. OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.
(FI) SISÄLTÖ ON STERIILI. Jos tämä pakkaus on avaamaton ja vahingoittumaton. VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.
(SV) INNEHÅLLET STERILT. Utom om förpackningen har öppnats eller skadats. VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.
(TR) Paket açılmamış yada zarar görmemişse MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.
(JA) 内容物は滅菌済み。包装が開封または破損していない限り。注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。
(ZH) 成份無菌。除非包裝被打開或損毀。注意：避免接觸潛在燃燒源。現場有可燃麻醉劑時不要使用。無天然膠乳。

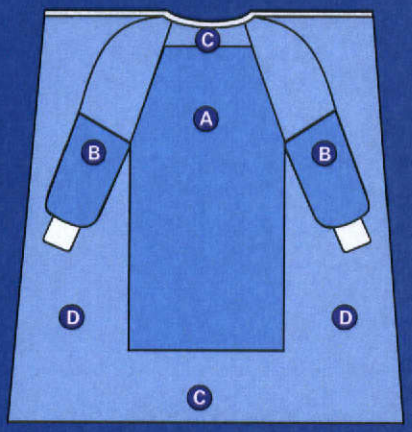
401

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

The Ultra Surgical Gown Product Brochure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016



AAMI Liquid Barrier Standard: Now for ULTRA Surgical Gowns

- **AAMI Level 3:**

  ULTRA Surgical Gowns provide Level 3 liquid barrier in zones A, B, and C

- **AAMI Level 4:**

  The ULTRA Film-Reinforced Surgical Gowns provide Level 4 liquid barrier in zones A, B, and C

[1]ANSI/AAMI PB70:2003 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

KIMBERLY-CLARK* ULTRA Gowns Meet AAMI Liquid Barrier Standard[1]

The liquid barrier standard for classification of protective apparel and drapes for use in hospital facilities has been introduced by the Association for the Advancement of Medical Instrumentation (AAMI) to assist healthcare personnel in the selection and use of surgical gowns, drapes, and other protective apparel.

The AAMI Liquid Barrier Standard is used widely and is now recognized by the FDA as a standard for barrier testing, classification, performance claims, and product labeling of surgical gowns.

AAMI: Defining the Critical Zones

AAMI liquid barrier performance levels are classified from Level 1 through Level 4, with Level 4 being the highest liquid barrier level. These levels apply to the product's Critical Zones. For surgical gowns, the critical zones are, at a minimum, the front area of the gown from chest to knees (area A) and the sleeves from the cuff to above the elbow (area B). The standard requires that the entire front of a surgical gown (Areas A, B, and C) provide a liquid barrier of at least Level 1. The back of the gown (area D) may be non-protective.

AAMI Classification of liquid barrier performance of surgical gowns, surgical drapes and drape accessories

Level	Test	Description	Result	AQL requirement
1	AATCC 42:2000	Impact penetration	≤ 4.5 g	4%
2	AATCC 42:2000 AATCC 127:1998	Impact penetration Hydrostatic pressure	≤ 1.0 g ≥ 20 cm	4% 4%
3	AATCC 42:2000 AATCC 127:1998	Impact penetration Hydrostatic pressure	≤ 1.0 g ≥ 50 cm	4% 4%
4	ASTM F1671:2003	Resistance to bacteriophage (surgical gowns and other protective apparel)	Pass	4%
	ASTM F1670:2003	Resistance to synthetic blood (surgical drapes and drape accessories)	Pass	4%

DRAFT

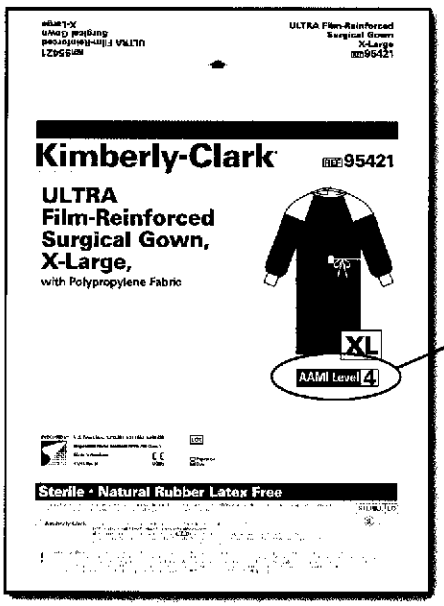
Kimberly-Clark

*Trusted Clinical Solutions**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

H03

OIA Request # 2015-9647; Released by CDRH on 03-28-2016



"At the shelf" selection is where AAMI liquid barrier classification provides its greatest benefit, through informative product labeling. You will find the AAMI level clearly indicated on each gown package and case label. In addition, the AAMI level is stamped on the inside of each gown.

AAMI Level 4

"Surgical gowns and drapes should be resistant to penetration by blood and other bodily fluids as necessitated by their intended use. Ultimately, blood and other bodily fluids are vehicles for bacterial and viral transmission."

— AORN 2004 Standards, Recommended Practices and Guidelines

DRAFT

Commitment to Excellence

If, for any reason, our products do not meet your expectations, please let us know your comments or suggestions for improvement. Your input will result in a concerted effort on our part to meet your requirements. Our goal is to provide quality products that completely meet your needs time after time.

For more information, please call your sales representative, or visit our web site at www.kchealthcare.com.

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H0707-07-01

Kimberly-Clark
*Trusted Clinical Solutions**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

404

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

2-Label Set (Box and Package)
Representative for the ULTRA Surgical Gown

(for Reference No. 95101, Small)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

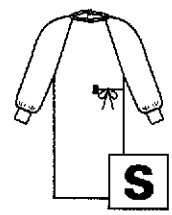
6"

6.75"

Kimberly-Clark*

ULTRA Surgical Gown, Small

with Polypropylene Fabric



AAMI Level 3

34

(34 x 1)

Single Use Only

REF **95101 35**

STERILE EO

Kimberly-Clark

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Sponsored in Australia by Kimberly-Clark Australia Pty Limited; 52 Alfred Street, Milsons Point, NSW 2061 • 1-800-101-021
製造販売元　キンバリー・クラーク・ヘルスケア インク　薬事申請名義人あらいに上記番号

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LOT

Expiration Date

Made in Honduras

00000000000

CE 0086

1"

DRAFT

5/27/08 • THERMAL CASE LABEL • 6" x 6.75"

BLUE items are preprinted on previously approved label shell

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

H06

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Surgical Gown
Small
REF 95101

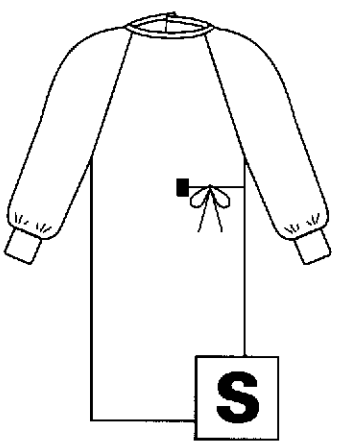
ULTRA Surgical Gown
Small
REF 95101

Kimberly-Clark*

REF 95101

ULTRA Surgical Gown, Small

with Polypropylene Fabric



AAMI Level 3

EVOLUTION* U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

Disposable: Flame Resistant NFPA 702 Class 1

Made in Honduras

49-63-2874-0-00

CE 0086

LOT

Expiration Date

(01) 1 06 86653 95101 1

Sterile • Natural Rubber Latex Free

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製造販売元：キンバリークラーク・ヘルスケア・インク　構造市場アメリカ合衆国　二桁2番1号

Cautions on Back • Precautions au dos • Sicherheitshinweise auf der Rückseite • Виж предупреждения на гръб • Consulte las precauciones al reverso • Upozornění na zadní straně • Advarsler på bagsiden • Hoitatused tagaküljel • Προειδοποιήσεις στην πίσω πλευρά • Avvertenze a tergo • Piesardzības noteikumi aizmugurē • Įspėjimai ant pakuotės nugarėlės • Figyelmeztetések a hátoldalon • Waarschuwingen op de achterkant • Forsiktighetsregler finnes på baksiden • Przestrogi na tyle • Cuidados atrás • Avertisment pe verso • Мере предосторожности - на обороте • Upozornenia vzadu • Svarila na zadnej strane • Varmistukset kaantopuolella • Forsiktighetsåtgärder på baksidan • Uyarılar ürün paketini arkasına bakınız • 注意事項は裏面

5/27/08
Form, Fill & Seal Package (primary package)
Black is in-line imprint
Blue is shell that has been previously approved

DRAFT

407

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

2-Label Set (Box and Package)
Representative for the ULTRA Surgical Gown, Two-Pack

(for Reference No. 95055, Large, Two-Pack)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

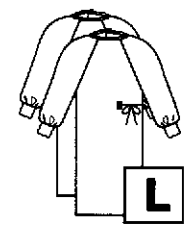
6"

6.75"

Kimberly-Clark*

ULTRA Surgical Gown, Large

with Polypropylene Fabric Two-Pack



AAMI Level 3

32

(16 x 2)

Single Use Only

REF **95055 25**

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LOT

Expiration Date

Made in Honduras

00000000000

CE 0086

1"

DRAFT

5/27/08 • THERMAL CASE LABEL • 6" x 6.75"

BLUE items are preprinted on previously approved label shell

409

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Surgical Gown
Large
Two-Pack
REF 95055

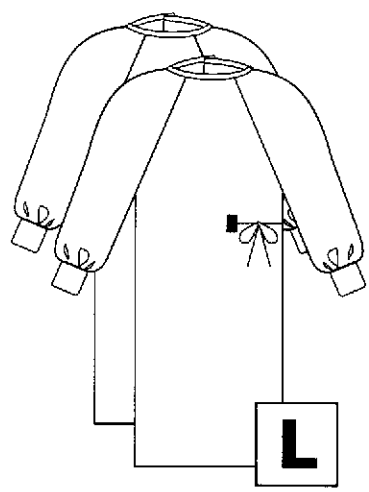
ULTRA Surgical Gown
Large
Two-Pack
REF 95055

Kimberly-Clark*

REF 95055

ULTRA Surgical Gown, Large

with Polypropylene Fabric Two-Pack



AAMI Level 3

EVOLUTION* U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688
Disposable; Flame Resistant NFPA 702 Class 1
Made in Honduras
49-63-899-0-00
CE 0086
LOT
Expiration Date

Sterile • Natural Rubber Latex Free

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必要情报元：キンバリー・クラーク・ヘルスケア・インク 東京中央区みなとみらい二丁目12番1号

Cautions on Back • Précautions au dos • Sicherheitshinweise auf der Rückseite • Виж предупреждения на гърба • Consulte las precauciones al reverso • Upozornění na zadní straně • Advarsler på bagsiden • Hoiatused tagaküljel • Προειδοποιητικά στην πίσω πλευρά • Avvertenze a tergo • Piesardzības noteikumi aizmugurē • Įspėjimai ant pakuotės nugarėlės • Figyelmeztetések a hátoldalon • Waarschuwingen op de achterkant • Forsiktighetsregler finnes på baksiden • Przestrogi na tyle • Cuidados atrás • Avertismenti pe verso • Мера предосторожности • на обратной • Upozornenia vzadu • Svarila na zadnej strane • Varoitukset kääntöpuolella • Forsiktighetsråder på baksiden • Uyarılar için paketin arkasına bakınız • 注意事項は裏面

DRAFT

5/27/08
Form, Fill & Seal Package (primary package)
Black is in-line imprint
Blue is shell that has been previously approved

410

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

2-Label Set (Box and Package)
Representative for the ULTRA Film-Reinforced Surgical Gown

(for Reference No. 95431, XXL)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

A11

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

ULTRA Film-Reinforced Surgical Gown, XX-Large

with Polypropylene Fabric

AAMI Level 4

30

(30 x 1)

Single Use Only

REF **95431** **15**

STERILE EO

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Sponsored in Australia by Kimberly-Clark Australia Pty Limited; 52 Alfred Street, Milsons Point, NSW 2061 • 1 800-101-021
我邦販売元 キンバリークラーク・ヘルスケア・インク 横浜市港北区みなとみらい二丁目2番1号

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LOT

Expiration Date

Made in Honduras

00000000000

CE 0086

1"

DRAFT

5/27/08 • THERMAL CASE LABEL • 6" x 6.75"

BLUE items are preprinted on previously approved label shell

412

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Film-Reinforced
Surgical Gown
XX-Large
REF 95431

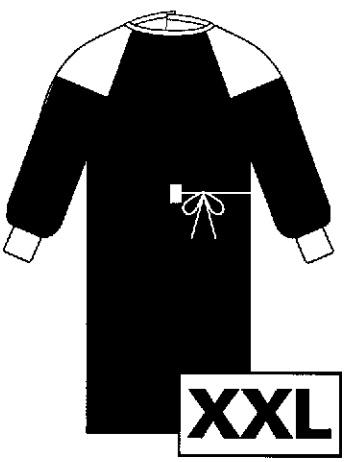
ULTRA Film-Reinforced
Surgical Gown
XX-Large
REF 95431

Kimberly-Clark*

REF 95431

ULTRA Film-Reinforced Surgical Gown, XX-Large

with Polypropylene Fabric



AAMI Level 4

MicroCool* Surgical Gowns pass ASTM F 1671, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration of Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System.

EVOLUTION* U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

Disposable; Flame Resistant NFPA 702 Class 1

Made in Honduras

91266 Rev 03

CE 0086

LOT

Expiration Date

(01) 1 06 80653 95431 4

Sterile • Natural Rubber Latex Free

*Registered Trademark or Trademark of Kimberly-Clark Worldwide, Inc. or its affiliates. *EVOLUTION and the WIRL-WLAVL Fabric Design are Registered Trademarks or Trademarks of KCWW. © 2004 KCWW. All Rights Reserved. 10-00-204-0-03

STERILE EO

Single Use Only

Kimberly-Clark

Distributed in the U.S. by Kimberly-Clark Global Sales, Inc., Roswell, GA 30076 USA
In USA, please call 1-800-KCHELPS • www.kchealthcare.com
Kimberly-Clark, Roswell, GA 30076 USA; EC REP Kimberly-Clark N.V., Belgicastraat 13, 1930 Zaventem, Belgium
Sponsored in Australia by Kimberly-Clark Australia Pty Limited; 52 Alfred Street, Milsons Point, NSW 2061 • 1-800-101-021
製造販売元 キンバリー クラーク ケアー・インク 横浜市港北区みなとみらい 1丁目12番1号

Cautions on Back • Précautions au dos • Sicherheitshinweise auf der Rückseite • Виж предупреждения на гърба • Consulte las precauciones al reverso • Upozornění na zadní stranę • Advarsler på bagsiden • Hoiatused tagaküljel • Προειδοποιήσεις στην πίσω σελίδα • Avvertenze a tergo • Piesardzības noteikumi aizmugurē • Įspėjimai ant pakuotės nugarėlės • Figyelmeztetések a hátoldalon • Waarschuwingen op de achterkant • Forsiktighetsregler finnes på baksiden • Uwagi na tyle • Cuidados atrás • Avertisment pe verso • Мерки предосторожности • на обороте • Upozornenia vzadu • Svarila na zadnji strani • Varoitukset kääntöpuolella • Forsiktighetsråder på baksiden • Uyarılar için paketin arkasına bakınız • 注意事項は裏面 • 注意事項在背面

DRAFT

5/2708
Form, Fill & Seal Package (primary package)
Black is in-line imprint
Blue is shell that has been previously approved

413

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

2-Label Set (Box and Package)
Representative for the ULTRA Film-Reinforced Specialty Surgical Gown

(for Reference No. 95511, L)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

ULTRA Film-Reinforced Specialty Surgical Gown, Large

with Polypropylene Fabric

AAMI Level 4

30

(30 x 1)

Single Use Only

REF **95511 35**

STERILE EO

Kimberly-Clark

In USA, please call 1-800-KCHELPS • www.kchealthcare.com

LOT

Expiration Date

Made in Honduras

00000000000

CE 0086

1"

DRAFT

5/29/08 • THERMAL CASE LABEL • 6" x 6.75"

BLUE items are preprinted on previously approved label shell

415

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Film-Reinforced
Specialty Surgical Gown
Large
REF 95511

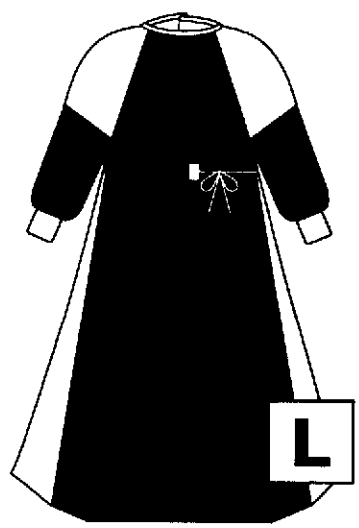
ULTRA Film-Reinforced
Specialty Surgical Gown
Large
REF 95511

Kimberly-Clark

REF 95511

ULTRA Film-Reinforced Specialty Surgical Gown, Large

with Polypropylene Fabric



AAMI Level 4

EVOLUTION®

U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688; 4,535,481

Disposable: Flame Resistant NFPA 702 Class 1

Made in Honduras

49-63-902-0-00

CE 0086

LOT

Expiration Date

Sterile • Natural Rubber Latex Free

STERILE EO

2

Kimberly-Clark

DRAFT

5/29/08
Form, Fill & Seal Package (primary package)
Black is in-line imprint

416

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attachment 5

Revised 510(k) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

510(k) Summary for the ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown

Intended Use: The Kimberly-Clark* ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gown meets Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gown meets Level 4 of the AAMI Liquid Barrier classifications.

Device Description: The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are full-length, nonwoven SMS polypropylene gowns. They are constructed with raglan sleeves, hook-and-loop neck closures, and tie waist closures. The ULTRA Film-Reinforced Surgical Gown is film-reinforced for higher barrier protection. The ULTRA Surgical Gown fully meets the Association for the Advancement of Medical Instrumentation (AAMI) Level 3 requirements for liquid barrier performance. The ULTRA Film-Reinforced Surgical Gown fully meets the AAMI Level 4 requirements for liquid barrier performance.

Substantial Equivalence: The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown are substantially equivalent to the predicate Kimberly-Clark KIMGUARD* and SPUNGUARD* Surgical Gowns in intended use, design, materials, and biocompatibility attributes. The performance attributes of the ULTRA gowns are substantially equivalent to the predicate gowns with the exception that the ULTRA Surgical Gown meets the requirements of AAMI Level 3 liquid barrier requirements and the ULTRA Film-Reinforced Surgical Gown meets the requirements of AAMI Level 4 liquid barrier requirements. The ULTRA gowns and their predicates are provided sterile and for single use.

Summary of Testing: The ULTRA Surgical Gown has been tested in compliance with the requirements of Level 3 liquid barrier performance requirements of ANSI/AAMI PB70: 2003 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities." The ULTRA Film-Reinforced Surgical Gown has been tested in compliance with the requirements of Level 4 liquid barrier performance requirements of ANSI/AAMI PB70: 2003. The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown also meet the requirements of the National Fire Protection Association (NFPA) Test Method 702-1980 for Class I. The ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown have been tested in compliance with the biocompatibility requirements of ISO 10993 for surface devices with limited contact with breached or compromised surfaces.

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* Registered Trademark or Trademark of Kimberly-Clark Worldwide, Inc. or its affiliates.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 19, 2008

KIMBERLY-CLARK CORP.
1400 HOLCOMB BRIDGE RD.
BLDG 300, #1092
ROSWELL, GA 30076
ATTN: DAVID M. LEE

510(k) Number: K080795
Product: ULTRA SURGICAL GOWN & FLUID BARRIER SURGICAL GOWN

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Kimberly-Clark
Received under Freedom of Information Act, FDA Request # 2015-9647; Released by CDRH on 03-28-2016

K080795 S2

8/15/2008

Terrell Cunningham
Nurse Consultant/Reviewer
FDA/CDRH/ODE/DAGID/ICDB
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850
(240) 276-3766
(301) 480-3002 Fax
terrell.cunningham@fda.hhs.gov

FDA CDRH DMC
AUG 19 2008
Received

Re: K080795 ULTRA Surgical Gown and ULTRA Film-Reinforced Surgical Gown with AAMI Liquid Barrier Level 3 and 4 claims.

Dear Mr. Cunningham,

On 13 June 2008 Kimberly-Clark Corporation (KCC) received your email Memorandum listing three deficiencies requiring resolution before you can make a substantial equivalence recommendation for the referenced 510(k) under review. Please note that the surgical gowns subject to this 510(k) submission are currently marketed under (b)(4)

(b)(4)

[redacted]

We have included the full text of all three deficiencies below in bold, and follow each deficiency with our response.

(b)(4)

[redacted]

1C42

22

Kimberly-Clark Corporation 1400 Holcomb Bridge Road Roswell, Georgia 30076
(770) 587-8000

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

(b)(4) Deficiencies

[redacted]

Please contact me if I can be of further assistance.

Sincerely,

David M. Lee
Associate Director of Regulatory Affairs
Phone: 770 587 7167
FAX: 920 225 4784
David.Lee@kcc.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form 3514
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
8/14/2008	not applicable, additional information related to 510(k) submitted under (b)(4) Drawings	K080795

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Kimberly-Clark Corporation	Establishment Registration Number *(if known)* 1033422		
Division Name *(if applicable)*	Phone Number *(including area code)* (770) 587 7167		
Street Address 1400 Holcomb Bridge Road Building 300, #1092	FAX Number *(including area code)* (920) 225 4784		
City Roswell	State / Province GA	ZIP/Postal Code 30076-2199	Country USA
Contact Name David M. Lee			
Contact Title Associate Director of Regulatory Affairs	Contact E-mail Address David.Lee@kcc.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)* ( )		
Street Address	FAX Number *(including area code)* ( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Sterilization
  - [ ] Packaging
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Response to FDA correspondence:

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Repose to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:
  This is additional information for 510(k) review K080795. The date of the original 510(k) submission was 3/17/08.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FYA	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

formation on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K781682	1	KIMGUARD* Surgical Gowns and Drapes	1	Kimberly-Clark*
2	K842115	2	SPUNGUARD Surgical Gowns and Drapes	2	Kimberly-Clark*
3	K861600	3	SPUNGARD Plus Surgical Gown	3	Kimberly-Clark*
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
surgical gown

	Trade or Proprietary or Model Name for This Device		Model Number
	ULTRA Surgical Gown	1	not applicable
2	ULTRA Film-Reinforced Surgical Gown	2	not applicable
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
K781682	K842115	K861600			
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
FYA	878.4040	☐ Class I ☒ Class II
Classification Panel: General & Plastic Surgery		☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Kimberly-Clark* ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gowns meet Level 4 of the AAMI Liquid Barrier assifications.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

APPENDIX I

Device labeling of those surgical gowns currently commercially distributed by KCC under K781682 and K842115 which **serve as the predicate devices** for the Ultra Surgical Gowns and Ultra Film-Reinforced Gowns under submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

PREDICATE DEVICE LABELING FOR THE ULTRA SURGICAL GOWNS WITH AAMI LEVEL 3 LIQUID BARRIER CLAIMS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

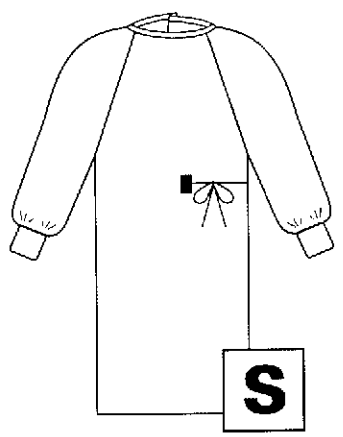
ULTRA Surgical Gown
Small
REF 95101

ULTRA Surgical Gown
Small
REF 95101

REF 95101

ULTRA Surgical Gown, Small,

with Towel



EVOLUTION™ U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

CE 0086

Made in Honduras

99859 Rev 01

LOT

Expiration Date

(01) 1 06 60651 951011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

40

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Kimberly-Clark*

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Cautions on Back Precautions au dos Sicherheitshinweise auf der Rückseite Вже попередження на звороті Consulte las precauciones al reverso Upozornění na zadní straně Advarsler på bagsiden Hátoldalon Ispėjimai ant pakuotės nugarėlės Figyelmeztetések a hátoldalon Waarschuwingen op de achterkant Forsiktighetsregler finnes på baksiden Przestrzegać na tyle Cuidados atrás Avertisment pe verso Мера предосторожности на обороте Upozornenia vzadu Svarila na zadnej strani Varoitukset kaantopuolella Forsiktighetsatgarder på baksidan Uyarılar için paketin arkasına bakınız 注意事項は裏面にあります 注意事項在背面

4/5/07
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Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

41

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4/5/07
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Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

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(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
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(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Iznņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
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(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din cauciuc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
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(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**
(JA) **内容物は滅菌済み。**包装が開封または破損していない限り。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(ZH) **成分无菌。**除非包装被打开或损坏。**注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然胶乳。**

42

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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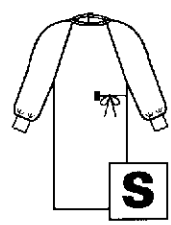
ULTRA Surgical Gown, Small



34
(34 x 1)

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REF **95101 25**

STERILE EO

LOT

Expiration Date

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(01) 3 0680651 95101 5(10) (30)34

CE
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43

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6" x 6.75"
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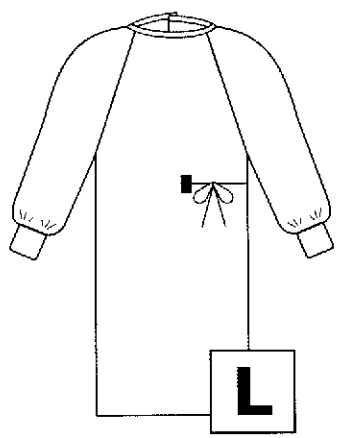
ULTRA Surgical Gown
Large
REF 95111

ULTRA Surgical Gown
Large
REF 95111

REF 95111

ULTRA Surgical Gown, Large,

with Towel



EVOLUTION+ U.S. Patent Nos.: 5,213,881; 5,271,988; 5,464,688

CE 0086
Made in Honduras
99860 Rev 01

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4/5/07
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Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

46

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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Medium Top Web - Back (rotated 180°)
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(ZH) **成分无菌。**除非包装被打开或损坏。**注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然胶乳。**

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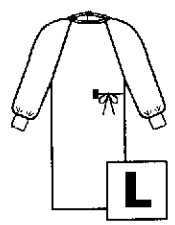
ULTRA Surgical Gown, Large



32
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REF **95111 25**

STERILE EO

LOT

Expiration Date

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CE 0086

42

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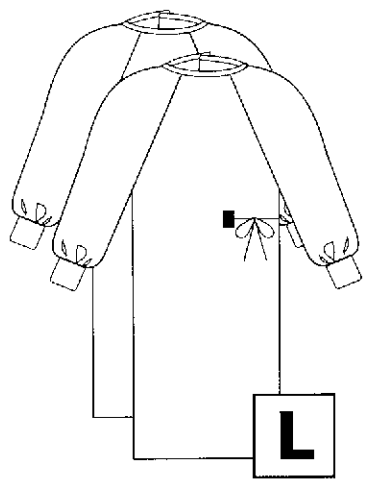
ULTRA Surgical Gown
Two-Pack
Large
REF 95055

ULTRA Surgical Gown
Two-Pack
Large
REF 95055

REF 95055

ULTRA Surgical Gown, Two-Pack Large,

with Towels



EVOLUTION™ U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

CE 0086
Made in Honduras
91271 Rev 02

LOT
Expiration Date

(01) 1 04 80651 950557

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

50

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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4/5/07
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2 x 2 Cutting Die
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

51

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
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2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**

(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**

(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**

(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**

(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

(LV) **STERILS SASTĀVS.** Iznņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot vieglī uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**

(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**

(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**

(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**

(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anestezicelor inflamabile. Produsul nu conține latex din cauciuc natural.**

(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**

(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

(FI) **SISÄLTÖ ON STERILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**

(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.**

(JA) **内容物は滅菌済み。**包装が開封または破損していない限り。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**

(ZH) **成分无菌。**除非包装被打开或损坏。**注意：避免接触在燃烧源，现场有可燃麻醉剂时不要使用，无天然胶乳。**

52

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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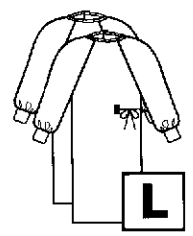
ULTRA Surgical Gown, Two-Pack, Large



32
(16 x 2)

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REF **95055 15**

STERILE EO

LOT

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(01) 3 0680651 95055 1(10) (30)32

CE 0086

53

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6"

6.75"

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
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54

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

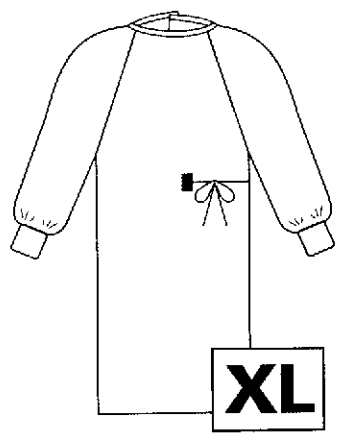
ULTRA Surgical Gown
X-Large
REF 95121

ULTRA Surgical Gown
X-Large
REF 95121

REF 95121

ULTRA Surgical Gown, X-Large,

with Towel



EVOLUTION®

U.S. Patent Nos.:
5,213,881;
5,771,883;
5,464,688

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(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**
(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**
(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**
(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Izņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**
(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**
(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anestezicelor inflamabile. Produsul nu conține latex din cauciuc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**
(JA) **内容物は滅菌済み。**包装が開封または破損していない限り。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(ZH) **成分无菌。**除非包装被打开或损坏。**注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然胶乳。**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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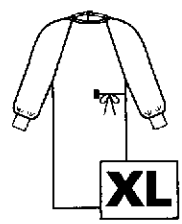
ULTRA Surgical Gown, X-Large



30
(30 x 1)

Single Use Only

REF **95121 25**

STERILE EO

LOT

Expiration Date

(01) 3 0680651 95121 3(10) (30)30

Made in Honduras

CE 0086

58

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

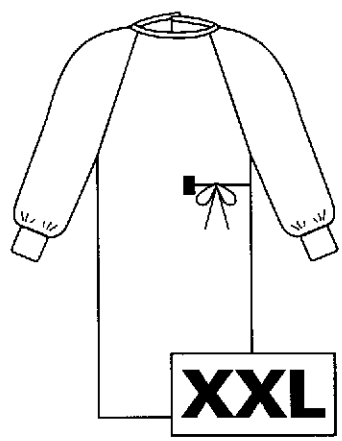
ULTRA Surgical Gown
XX-Large
REF 95131

ULTRA Surgical Gown
XX-Large
REF 95131

REF 95131

ULTRA Surgical Gown, XX-Large,

with Towel



EVOLUTION®

U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

CE 0086

Made in Honduras

99861 Rev 01

LOT

Expiration Date

6/28/07
Form, Fill & Seal Package (primary package)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

60

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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STERILE EO

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Cautions on Back Precautions au dos Sicherheitshinweise auf der Rückseite Важ предупреждения на гръб Consulte las precauciones al reverso Upozornění na zadní straně Advarsler på bagsiden Hoiatused tagakiljel Προειδοποιήσεις στην πίσω πλευρά Avvertenze a tergo Piesardzības noteikumi aizmugure Įspėjimai ant pakuotės nugarėlės Figyelmeztetések a hátoldalon Waarschuwingen op de achterkant Forsiktighetsregler finnes på baksiden Przestrogi na tyle Cuidados atrás Avertisment pe verso Мерки предосторожности - на обратно Upozornenia vzadu Svarila na zadnej strani Varoitukset kääntöpuolella Försiktighetsåtgärder på baksidan Uyarılar için paketin arkasına bakınız 注意事項は裏面に 注意事項在背面

4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**
(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**
(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**
(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Izņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**
(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**
(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anestezicelor inflamabile. Produsul nu conține latex din cauciuc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**
(JA) **内容物は滅菌済み。**包装が開封または破損していない限り。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(ZH) **成分无菌。**除非包装被打开或损坏。**注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然胶乳。**

62

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Surgical Gown, XX-Large

28
(28 x 1)

Single Use Only

REF **95131** **25**

STERILE EO

LOT

Expiration Date

Made in Honduras

(01) 3 0680651 95131 2(10) (30)28

CE 0086

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

63

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

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[illegible]

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

64

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

PREDICATE DEVICE LABELING FOR THE ULTRA FILM-REINFORCED GOWNS WITH AAMI LEVEL 4 LIQUID BARRIER CLAIMS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

REF 95411
ULTRA Impervious
Surgical Gown
Large

ULTRA Impervious
Surgical Gown
Large
REF **95411**

REF **95411**

ULTRA Impervious Surgical Gown, Large, with Towel

ULTRA OP-Kittel, undurchlässig, L, mit Handtuch

Casaque chirurgicale ULTRA étanche, L, avec serviette

ULTRA ondoorlatende operatiejas, L, met handdoek

Camice chirurgico impermeabile ULTRA, L, con asciugamano

Bata quirúrgica impermeable ULTRA, L, con toalla

Bata cirúrgica impermeável ULTRA, L, com toalha

ULTRA ugjennomtrengelig operasjonsfrakk, L, med håndkle

ULTRA ogenomtränglig kirurgiskyddsrock, L, med handduk

ULTRA läpäisemätön leikkaustakki, L, mukana käsipyyhe

ULTRA vandtæt operationskittel, L, med håndklæde

Αδιαπερατή Χειρουργική Ποδιά ULTRA, L, με Πετσέτα

ウルトラ防水サージカルガウン　L　タオル入
滅菌済・一回限り使用
輸入・販売元・キンバリークラークPHCインターナショナルインク
横浜市西区みなとみらい 2-3-1 クイーンズタワー A

EVOLUTION® U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688; 5,188,885

LOT

Made in Honduras

91755 Rev 01

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66

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製品販売元：キンバリー・クラーク・ヘルスケア・インク（詳細は裏面をご覧ください。）12番11

Cautions on Back Précautions au dos Sicherheitshinweise auf der Rückseite Диж предупреждения на гърба Consulte las precauciones al reverso Upozornění na zadní straně Advarsler på bagsiden Hoiatused tagaküljel Προειδοποιησεις στην πισω πλευρα Avvertenze a tergo Piesardzības noteikumi aizmugure Įspėjimai ant pakuotės nugarėlės Figyelmeztetések a hátoldalon Waarschuwingen op de achterkant Forsiktighetsregler finnes på baksiden Przestrogi na tyle Cuidados atrás Avertisment pe verso Мерки предосторожности - на обратте Upozornenia vzadu Svarila na zadnej strani Varoituksel käänteipuolella Försiktighetsåtgärder på baksidan Uyarılar için paketin arkasına bakınız 使用上の注意は裏面にあります。 注意事項在背面

4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

(DE) **STERIL,** solange die Packung nicht geöffnet oder beschadigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**

(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**

(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**

(DK) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**

(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

(LV) **STERILS SASTĀVS.** Iznnemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**

(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**

(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**

(NO) **STERILT INNHOLD.** Steriile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**

(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziicelor inflamabile. Produsul nu conține latex din cauciuc natural.**

(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**

(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

(SI) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**

(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.**

(JA) **内容物は滅菌済み**（包装が開封または破損していない限り）。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**

(CH) **成分无菌。**除非包装被打开或损坏。**注意：避免接触在燃烧源　现场有可燃麻醉剂时不要使用　无天然胶乳。**

62

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Impervious Surgical Gown, Large
ULTRA OP-Kittel, undurchlässig, L
Casaque chirurgicale ULTRA étanche, L
ULTRA ondoorlatende operatiejas, L
Camice chirurgico impermeabile ULTRA, L
Bata quirúrgica impermeable ULTRA, L
Bata cirúrgica impermeável ULTRA, L
ULTRA ugjennomtrengelig operasjonsfrakk, L
ULTRA ogenomtränglig kirurgiskyddsrock, L
ULTRA läpäisemätön leikkaustakki, L LOT
ULTRA vandtæt operationskittel, L
Αδιαπερατή Χειρουργική Ποδιά ULTRA, L
ウルトラ防水サージカルガウン　L

Single Use Only
一回限り使用

REF **95411** **00**

Made in Honduras

輸入・販売元・キンバリークラーク
PHCインターナショナルインク

滅菌済 STERILE EO

(01) 3 0680651 95411 5(10) (30)34

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6"

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1"

4/5/07
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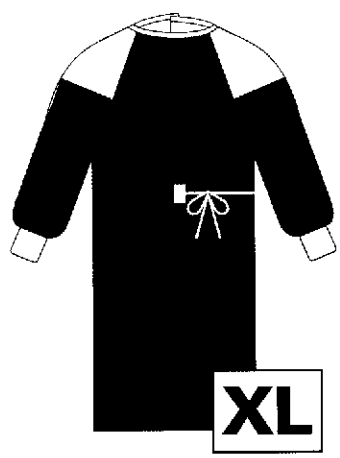
REF 95421
ULTRA Impervious
Surgical Gown
X-Large

ULTRA Impervious
Surgical Gown
X-Large
REF 95421

REF 95421

ULTRA Impervious† Surgical Gown, X-Large,

with Towel



†Passes ASTM F 1671, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration of Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System.

EVOLUTION† U.S. Patent Nos.: 5,213,681; 5,271,883; 5,464,688

CE 0086

Made in Honduras

91260 Rev 02

LOT

Expiration Date

(01) 1 04 60653 95421 0

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

71

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4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

72

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Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**
(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**
(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**
(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Iznņemot, ja iepakojums atvērts vai bojāls. **PIESARDZĪBA: Jālzsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**
(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**
(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anestezicelor inflamabile. Produsul nu conține latex din cauciuc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.**
(JA) **内容物は滅菌済み**。包装が開封または破損していない限り。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(ZH) **成分无菌**。除非包装被打开或损坏。**注意：避免接触在燃烧源　现场有可燃麻醉剂时不要使用　无天然胶乳。**

73

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ULTRA Impervious Surgical Gown, X-Large

32
(32 x 1)

Single Use Only

REF **95421 25**

STERILE EO

LOT

Expiration Date

Made in Honduras

(01) 3 0680651 95421 4(10) (30)32

CE 0086

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6"

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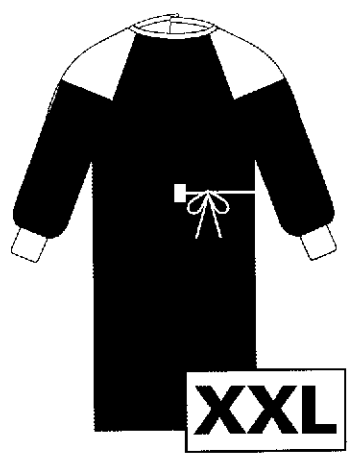
REF 95431
ULTRA Impervious
Surgical Gown
XX-Large

ULTRA Impervious
Surgical Gown
XX-Large
REF 95431

REF 95431

ULTRA Impervious† Surgical Gown, XX-Large,

with Towel



†MicroCool® Surgical Gowns pass ASTM F 1671, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration of Blood-Borne Pathogens Using Phi X174 Bacteriophage Penetration as a Test System.

EVOLUTION®

U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

CE 0086

Made in Honduras

91265 Rev 02

LOT

Expiration Date

(01) 1 06 80651 [illegible]

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76

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4/5/07
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2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
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(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**
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(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
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(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Iznņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**
(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**
(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEUDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din cauciuc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SI) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.**
(JA) **内容物は滅菌済み**（包装が開封または破損していない限り）。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(ZH) **成分无菌**。除非包装被打开或损坏。**注意：避免接触在燃烧源 现场有可燃麻醉剂时不要使用 无天然胶乳。**

78

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Impervious Surgical Gown, XX-Large

Single Use Only

REF 95431 15

STERILE EO

LOT

Expiration Date

Made in Honduras

(01) 3 0680651 95431 3(10) (30)30

CE 0086

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6"

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20

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

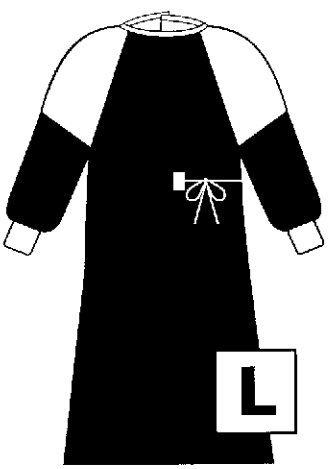
ULTRA Specialty Gown
Large
REF 95511

ULTRA Specialty Gown
Large
REF 95511

REF 95511

ULTRA Specialty Gown, Large,

with Towel



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U.S. Patent Nos.:
5,211,881;
5,271,883;
5,464,688;
4,535,491

Made in Honduras
91722 Rev 02

LOT

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21

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4/5/07
10-60-204-0-03
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2 x 2 Cutting Die
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

22

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
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2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**
(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**
(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**
(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Iznņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**
(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**
(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din caucluc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**
(JA) **内容物は滅菌済み。**包装が開封または破損していない限り。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(ZH) **成分无菌、除非包装被打开或损坏。注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然胶乳。**

83

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Specialty Gown, Large

30
(30 x 1)

Single Use Only

REF **95511** **20**

STERILE EO

LOT

Made in Honduras

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1"

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Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

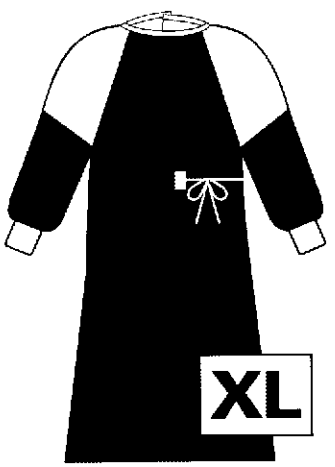
ULTRA Specialty Gown
X-Large
REF 95521

ULTRA Specialty Gown
X-Large
REF 95521

REF 95521

ULTRA Specialty Gown, X-Large,

with Towel



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U.S. Patent Nos.: 5,213,881; 5,271,893; 5,664,696; 4,535,481

CE 0086

Made in Honduras

89868 Rev 01

LOT

Expiration Date

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Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

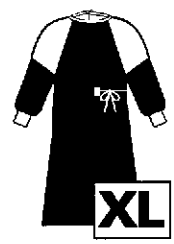
(EN) **CONTENTS STERILE**. Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE**. Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL**, solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**
(ES) **CONTENIDO ESTÉRIL**, a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**
(CS) **OBSAH JE STERILNÍ**, pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**
(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE**. Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS**. Izņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
(LT) **PAKUOTĖS TURINYS STERILUS**, kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**
(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**
(NL) **INHOUD STERIEL**. Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD**. Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY**. O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEÚDO ESTERILIZADO**. Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceelor inflamabile. Produsul nu conține latex din cauciuc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО**, если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ**, ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SL) **VSEBINA STERILNA**. Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI**. Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT**. Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**
(JA) **内容物は滅菌済み**。包装が開封または破損していない限り。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(ZH) **成分无菌**。除非包装被打开或损坏。**注意：避免接触在燃烧源　现场有可燃麻醉剂时不要使用　无天然胶乳。**

88

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Specialty Gown, X-Large



28
(28 x 1)

Single Use Only

REF **95521 25**

STERILE EO

LOT

Expiration Date

Made in Honduras

(01) 3 0680651 95521 1(10) (30)28

CE 0086

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

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In USA, please call 1-800-KCHELPS • www.kchealthcare.com
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Sponsored in Australia by Kimberly-Clark Australia Pty Limited; 52 Alfred Street, Milsons Point, NSW 2061 • 1-800-101-027
製造販売元：キンバリー・クラーク・ヘルスケア・インク　感染症お問合せ先：0120-[illegible]

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

90

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

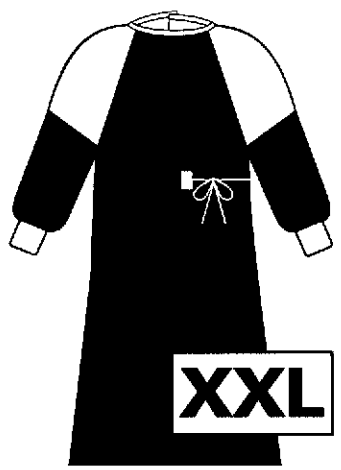
ULTRA Specialty Gown
XX-Large
REF 95531

ULTRA Specialty Gown
XX-Large
REF 95531

REF 95531

ULTRA Specialty Gown, XX-Large,

with Towel



EVOLUTION®

U.S. Patent Nos.: 5,213,881; 5,271,883; 5,484,688; 4,535,481

Made in Honduras

49-60-296-0-00

LOT

(01) 1 06 80651 95531L

8/16/07
Form, Fill & Seal Package (primary package)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sterile • Natural Rubber Latex Free

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STERILE EO

2 Single Use Only

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Sponsored in Australia by Kimberly-Clark Australia Pty Limited; 52 Alfred Street, Milsons Point, NSW 2061 • 1-800-101-021
製造販売元　キンバリークラーク・ヘルスケア・インク　徳島市西区みなとみらい二丁目12番1号

Cautions on Back / Précautions au dos / Sicherheitshinweise auf der Rückseite / Виж предупрежденията на гърба / Consulte las precauciones al reverso / Upozornění na zadní straně / Advarsler på bagsiden / Hoiatused tagaküljel / Προειδοποιήσεις στην πίσω πλευρά / Avvertenze a tergo / Piesardzības noteikumi aizmugurē / Įspėjimai ant pakuotės nugarėlės / Figyelmeztetések a hátoldalon / Waarschuwingen op de achterkant / Forsiktighetsregler finnes på baksiden / Przestrogi na tyle / Cuidados atrás / Avertisment pe verso / Мерки предосторожности - на обороте / Upozornenia vzadu / Svarila na zarinji strani / Varoitukset kaantopuolella / Försiktighetsåtgärder på baksidan / Uyarılar için paketin arkasına bakınız / 注意事項は裏面にあります / 注意事項在背面

4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

92

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**
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(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**
(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Iznņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
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(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
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(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien läheillä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
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(JA) **内容物は滅菌済み**、包装が開封または破損していない限り。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(ZH) **成分无菌、除非包装被打开或损坏。注意：避免接触在燃烧源　现场有可燃麻醉剂时不要使用　无天然胶乳。**

93

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Specialty Gown, XX-Large

Single Use Only

REF 95531 20

STERILE EO

LOT

Made in Honduras

(01) 3 0680651 95531 0(10) (30)28

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

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In USA, please call 1-800-KCHFLPS • www.kchealthcare.com
Kimberly-Clark, Roswell, GA 30076 USA; [illegible] Kimberly-Clark N.V., Belgicastraat 13, 1930 Zaventem, Belgium
Sponsored in Australia by Kimberly-Clark Australia Pty Limited; 52 Alfred Street, Milsons Point NSW 2061 • 1-800-101-0x1
製造販売元：キンバリークラーク・ヘルスケア・インク　[illegible]

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

APPENDIX II

Current labeling for sterile surgical gowns currently commercially distributed by KCC under K781682, K842115 and K861600 but which are **not used as predicate devices** for the Ultra Surgical Gowns and Ultra Film-Reinforced Gowns under submission.

- Surgical Gown
- Tie-back Fabric-Reinforced Surgical Gown
- Standard Surgical Gown
- Fabric-Reinforced Surgical Gown
- Ultra Zoned Impervious Surgical Gown
- Ultra Surgical Gown
- Ultra Fabric-Reinforced Surgical Gown

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Surgical Gown
Large
REF 90018

Surgical Gown
Large
REF 90018

REF 90018

Surgical Gown, Large, with Towel

OP-Kittel, L, mit Handtuch

Casaque chirurgicale, L, avec serviette

Operatiejas, L, met handdoek

Camice chirurgico, L, con asciugamano

Bata quirúrgica, L, con toallita

Bata Cirúrgica, L, com toalha

Operasjonsfrakk, L, med håndkle

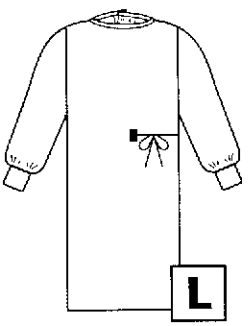
Kirurgiskyddsrock, L, med handduk

Leikkaustakki, L, mukana käsipyyhe

Operationskittel, L, med håndklæde

Χειρουργική Ποδιά, L, με Πετσέτα

サージカルガウン　L　タオル入
滅菌済・一回限り使用
輸入・販売元：キンバリークラークPHCインターナショナルインク
横浜市西区みなとみらい 2-3-1 クイーンズタワー A



EVOLUTION® U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

LOT

Made in Honduras

99853 Rev 00

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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Sterile • Natural Rubber Latex Free

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STERILE EO

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4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

98

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**

(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**

(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**

(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**

(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

(LV) **STERILS SASTĀVS.** Iznņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**

(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**

(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**

(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**

(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anestezicelor inflamabile. Produsul nu conține latex din cauciuc natural.**

(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**

(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**

(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.**

(JA) **内容物は滅菌済み**（包装が開封または破損していない限り）。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**

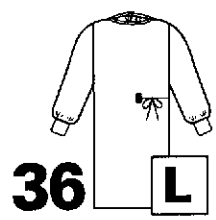
(ZH) **成分无菌。除非包装被打开或损坏。注意：避免接触在燃烧源　现场有可燃麻醉剂时不要使用　无天然胶乳。**

99

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Surgical Gown, Large
OP-Kittel, L
Casaque chirurgicale, L
Operatiejas, L
Camice chirurgico, L
Bata quirúrgica, L
Bata cirúrgica, L
Operasjonsfrakk, L
Kirurgiskyddsrock, L
Leikkaustakki, L
Operationskittel, L
Χειρουργική Ποδιά, L
サージカルガウン　L



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REF **90018 30**

LOT

Made in Honduras

(01) 3 0680651 90018 1(10) (30)36

100

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6"

6.75"

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

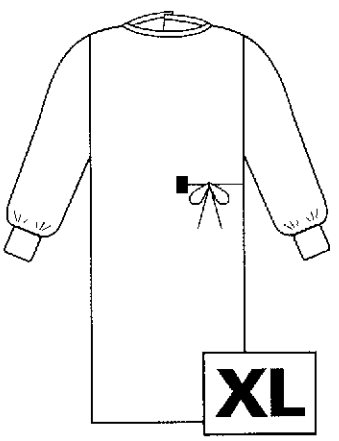
Surgical Gown
X-Large
REF 90048

Surgical Gown
X-Large
REF 90048

REF 90048

Surgical Gown, X-Large,

with Towel



EVOLUTION U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

CE 0086
Made in Honduras
99855 Rev 01

LOT

Expiration Date

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107

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4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

103

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

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(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

(LV) **STERILS SASTĀVS.** Iznnemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**

(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**

(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**

(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**

(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din cauciuc natural.**

(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**

(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

(SI) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**

(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**

(JA) **内容物は滅菌済み**（包装が開けまたは破損していない限り）。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**

(CH) **成分无菌**。除非包装被打开或损坏。**注意：避免接触在燃烧源　现场有可燃麻醉剂时不要使用　无天然橡乳。**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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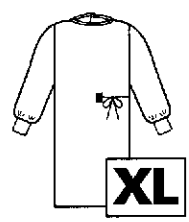
Surgical Gown, X-Large



32
(32 x 1)

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REF **90048 65**

STERILE EO

LOT

Expiration Date

Made in Honduras

(01) 3 0680651 90048 8(10) (30)32

CE 0086

105

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

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6" x 6.75"
Prints PMS 299 Blue

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Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

REF 90212
Tie-Back Fabric-Reinforced
Surgical Gown
Large

Tie-Back Fabric-Reinforced
Surgical Gown
Large
REF **90212**

REF **90212**

Tie-Back Fabric-Reinforced Surgical Gown, Large,
with Towel

OP-Kittel, gewebeverstärkt, am Rücken gebunden, L, mit Handtuch

Casaque chirurgicale nouée derrière, avec renfort en tissu, L,
avec serviette

Operatiejas van verstevigde stof met sluiting achter, L, met handdoek

Camice chirurgico con rinforzo in stoffa, allacciatura posteriore, L,
con asciugamano

Bata quirúrgica con tiritas, reforzada con tela, L, con toalla

Bata cirúrgica com reforço de tecido, para apertar atrás, L, com toalha

Stofforsterket operasjonsfrakk med knyting bak, L, med håndkle

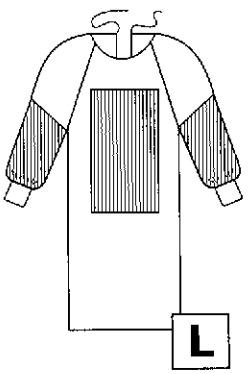
Textilförstärkt kirurgiskyddsrock som knyts fast bakom ryggen, L, storlek L, med handduk

Tekstiilivahvisteinen leikkaustakki, takaa nauhoilla kiinnitettävä, L,
mukana käsipyyhe

Operationskittel af slidstærkt stof, bindes på ryggen, L, med håndklæde

Χειρουργική Ποδιά Ενισχυμένη με Ύφασμα με δέσιμο στην πλάτη, L, με Πετσέτα

タイバック補強済サージカルガウン　L　タオル入
滅菌済・一回限り使用
輸入・販売元・ギンバリークラークPLCインターナショナルインク
横浜市西区みなとみらい 2-3-1 クイーンズタワー A



EVOLUTION® U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688; 5,188,885

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Cautions on Back Précautions au dos Sicherheitsrunweise auf der Rückseite Виж предупрежденията на гърба Consulte las precauciones al reverso Upozornení na zadní straně Advarsler på bagsiden Hoatused tagaküljel Προειδοποιήσεις στην πίσω πλευρά Avvertenze a tergo Priesardzības noteikumi aizmugurē Ispojmai ant pakuotės nugarėlės Figyelmeztetések a hátoldalon Waarschuwingen op de achterkant Forsiktighetsregler finnes på baksiden Przestrogi na tyle Cuidados atrás Avertisment pe verso Мерки предосторожности - на обратната страна Upozornenia vzadu Svarila na zadnej strani Varoitukset kääntöpuolella Försiktighetsåtgärder på baksidan Uyarılar için paketin arkasına bakınız 注意事項は裏面にあります 注意事项在背面

4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

108

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4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de sterilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

(DE) **STERIL,** solange die Packung nicht geöffnet oder beschadigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**

(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**

(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**

(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**

(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

(LV) **STERILS SASTĀVS.** Iznemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**

(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**

(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**

(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

(PT) **CONTEUDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**

(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din cauciuc natural.**

(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**

(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

(SI) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**

(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**

(JA) **内容物は滅菌済み**（包装が開封または破損していない限り）。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**

(CH) **成分无菌**、除非包装被打开或损坏。**注意：避免接触在燃烧源 现场有可燃麻醉剂时不要使用 无天然胶乳。**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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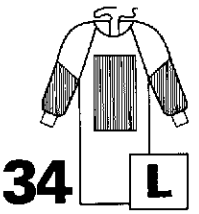
Tie-Back Fabric-Reinforced Surgical Gown, Large
OP-Kittel, gewebeverstärkt, am Rücken gebunden, L
Casaque chirurgicale nouée derrière, avec renfort en tissu, L
Operatiejas van verstevigde stof met sluiting achter, L
Camice chirurgico con rinforzo in stoffa, allacciatura posteriore, L
Bata quirúrgica con tiritas, reforzada con tela, L
Bata cirúrgica com reforço de tecido, para apertar atrás, L
Stofforsterket operasjonsfrakk med knyting bak, L
Textilförstärkt kirurgiskyddsrock som knyts fast bakom ryggen, L
Tekstiilivahvisteinen leikkaustakki, takaa nauhoilla kiinnitettävä, L
Operationskittel af slidstærkt stof, bindes på ryggen, L
Χειρουργική Ποδιά Ενισχυμένη με Ύφασμα με δέσιμο στην πλάτη, L
タイバック補強済サージカルガウン L



LOT

Single Use Only
一回限り使用

REF **90212** **30**

Made in Honduras

輸入・販売元・キンバリークラーク
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滅菌済 STERILE EO

(01) 3 0680651 90212 3(10) (30)34

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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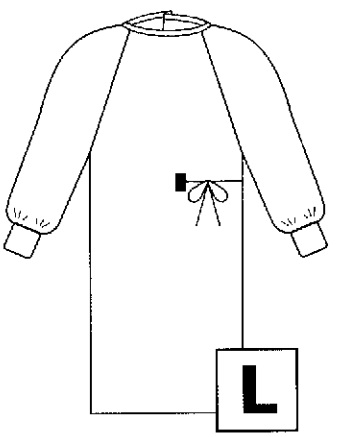
Standard Gown
Large
REF 90012

Standard Gown
Large
REF 90012

REF 90012

Standard Gown, Large,

with Towel



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U.S. Patent Nos.:
5,210,881;
5,271,883;
5,464,888

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4/5/07
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Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

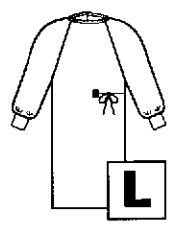
(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**
(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**
(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**
(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Iznemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot vielā uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**
(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**
(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din cauciuc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SI) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien läheillä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**
(JA) **内容物は滅菌済み**、包装が開封または破損していない限り。**注意**：**着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(CH) **成分无菌**，除非包装被打开或损坏。**注意**：**避免接触在燃烧源　现场有可燃麻醉剂时不要使用　无天然胶乳。**

114

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Standard Gown, Large



36
(36 x 1)

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REF **90012 35**

STERILE EO

LOT

Expiration Date

Made in Honduras

(01) 3 0680651 90012 9(10) (30)36

CE
0086

115

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
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116

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Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

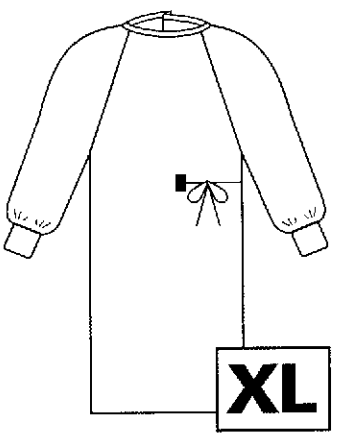
Standard Gown
X-Large
REF 90042

Standard Gown
X-Large
REF 90042

REF 90042

Standard Gown, X-Large,

with Towel



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CE 0086

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Cautions on Back Précautions au dos Sicherheitshinweise auf der Rückseite Виж предупрежденията на гърба Consulte las precauciones al reverso Upozornění na zadní straně Advarsler på bagsiden Hoiatused tagakülgel Προειδοποιήσεις στην πίσω πλευρά Avvertenze a tergo Piesardzības norādījumi aizmugurē Įspėjimai ant pakuotės nugarėles Figyelmeztetések a hátoldalon Waarschuwingen op de achterkant Forsiktighetsregler finnes på baksiden Przestrogi na tyle Cuidados atrás Avertisment pe verso Меры предосторожности - на обороте Upozornenia vzadu Svarila na zadnji strani Varoitukset kääntöpuolella Försiktighetsåtgärder på baksidan Uyarılar için paketin arkasına bakınız 注意事項は裏面にあります 注意事項在背面

4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

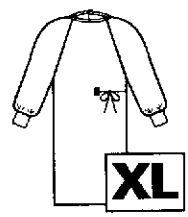
(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**
(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**
(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**
(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Iznņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**
(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**
(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONŢINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezenţa anestezicelor inflamabile. Produsul nu conţine latex din caucluc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**
(JA) **内容物は滅菌済み。**包装が開封または破損していない限り。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(ZH) **成分无菌。**除非包装被打开或损坏。**注意：避免接触在燃烧源　现场有可燃麻醉剂时不要使用　无天然胶乳。**

114

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Standard Gown, X-Large



34
(34 x 1)

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REF **90042 35**

STERILE EO

LOT

Expiration Date

Made in Honduras

(01) 3 0680651 90042 6(10) (30)34

CE 0086

120

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6"

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

121

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Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Surgical Gown
Large
REF 95011

REF 95011
Surgical Gown
Large

REF 95011

Surgical Gown, Large, with Towel

OP-Kittel, Large, mit Handtuch

Casaque chirurgicale, Large, avec serviette

Operatiejas, Large, met handdoek

Camice chirurgico, Large, con asciugamano

Bata quirúrgica, Grande, con toallita

Bata cirúrgica, Grande, com toalha

Operasjonsfrakk, Large, med håndkle

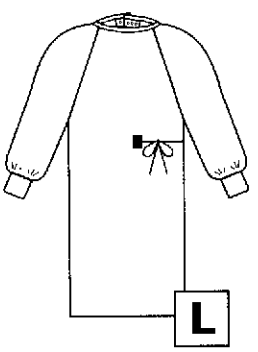
Operationsrock, storlek L, med handduk

Leikkaustakki, L, mukana käsipyyhe

Operationskittel, Large, med håndklæde

Χειρουγική Ποδιά, Μεγάλο, με Πετσέτα

サージカルガウン　L　タオル入
滅菌済・一回限り使用
輸入・販売元・キンバリークラークPHCインターナショナルインク
横浜市西区みなとみらい 2-3-1 クイーンズタワー A



EVOLUTION® U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688; 5,188,885

LOT

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99834 Rev 00

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4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

123

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

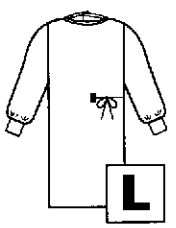
4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**
(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**
(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**
(DK) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Iznņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**
(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**
(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziicelor inflamabile. Produsul nu conține latex din caucluc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SI) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.**
(JA) **内容物は滅菌済み**（包装が開封または破損していない限り）。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(CH) **成分无菌**、除非包装被打开或损坏。**注意：避免接触在燃烧源　现场有可燃麻醉剂时不要使用　无天然胶乳。**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Surgical Gown, Large



32
(32 x 1)

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REF **95011 60**

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LOT

(01) 3 0680651 95011 7(10) (30)32

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6"

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4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

126

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REF 95021
Standard Gown
X-Large

Standard Gown
X-Large
REF 95021

REF 95021

Surgical Gown, X-Large, with Towel

OP-Kittel, XL, mit Handtuch

Casaque chirurgicale, XL, avec serviette

Operatiejas, XL, met handdoek

Camice chirurgico, XL, con asciugamano

Bata quirúrgica, XL, con toalla

Bata Cirúrgica, XL, com toalha

Operasjonsfrakk, XL, med håndkle

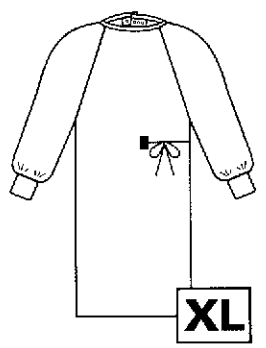
Kirurgiskyddsrock, XL, med handduk

Leikkaustakki, XL, mukana käsipyyhe

Operationskittel, XL, med håndklæde

Χειρουργική Ποδιά, XL, με Πετσέτα

サージカルガウン　XL　タオル入
滅菌済・一回限り使用
輸入・販売元・キンバリークラークPHCインターナショナルインク
横浜市西区みなとみらい 2-3-1 クイーンズタワー A



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U.S. Patent Nos.:
5,213,881;
5,271,883;
5,464,688;
5,188,885

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99895 Rev 00

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Cautions on Back Précautions au dos Sicherheitshinweise auf der Rückseite Виж предупрежденията на гърба Consulte las precauciones al reverso Upozornení na zadní straně Advarsler på bagsiden Hoitatused tagaküljel Προειδοποιήσεις στην πίσω πλευρά Avvertenze a tergo Piesardzības noteikumi aizmugurē Įspėjimai ant pakuotės nugarėlės Figyelmeztetések a hátoldalon Waarschuwingen op de achterkant Forsiktighetsregler finnes på baksiden Przestrogi na tyle Cuidados atrás Avertisment pe verso Мерѣ предосторожности - на обороте Upozornenia vzadu Svarila na zadnji strani Varoitukset käantöpuolella Försiktighetsåtgärder på baksidan Uyarılar için paketin arkasına bakınız 注意事項は後側にあります 注意事項在背面

4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

128

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Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zundquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**

(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**

(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**

(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**

(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

(LV) **STERILS SASTĀVS.** Iznņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jālzsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**

(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyulékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**

(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**

(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**

(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din caucluc natural.**

(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**

(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien läheillä. Ei sisällä luonnonkumilateksia.**

(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.**

(JA) **内容物は滅菌済み（パッケージが開けられていない場合）。注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**

(ZH) **成分无菌，除非包装被打开或损坏。注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然胶乳。**

129

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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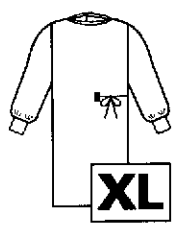
Surgical Gown, X-Large



30
(30 x 1)

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REF **95021 60**

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LOT

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6"

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1"

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20-61-504-0-06
6" x 6.75"
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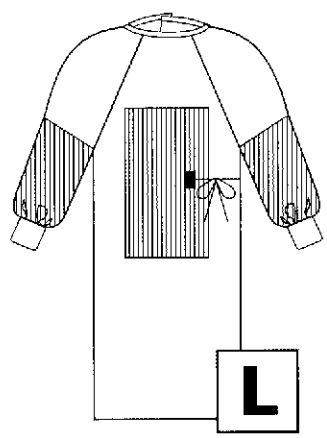
REF 90112
Fabric-Reinforced
Surgical Gown
Large

Fabric-Reinforced
Surgical Gown
Large
REF 90112

REF 90112

Fabric-Reinforced Surgical Gown, Large,

with Towel



EVOLUTION® U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

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LOT

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Sponsored in Australia by Kimberly Clark Australia Pty Limited; 52 Alfred Street, Milsons Point, NSW 2061 • 1-800-101-021
製造販売元　キンバリー・クラーク・ヘルスケア・インク　横浜市西区みなとみらい二丁目2番1号

Cautions on Back Precautions au dos Sicherheitshinweise auf der Rückseite Виж предупрежденията на гърба Consulte las precauciones al reverso Upozornění na zadní straně Advarsler på bagsiden Hoiatused tagaküljel Προειδοποιησεις στην πισω πλευρά Avvertenze a tergo Piesardzibas noteikumi aizmugure Įspėjimai ant pakuotės nugarėlės Figyelmeztetések a hátoldalon Waarschuwingen op de achterkant Forsiktighetsregler finnes på baksiden Przestrogi na tyle Cuidados atrás Avertisment pe verso Меры предосторожности - на обороте Upozornenia vzadu Svarila na zadnj strani Varoitukset käännöpuolella Försiktighetsåtgärder på baksidan Uyarılar için paketin arkasına bakınız 注意書きは後側にあります 注意事項在背面

4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

133

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

EN **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

FR **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu. Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

DE **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

BG **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**

ES **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**

CS **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**

DA **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**

ET **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

EL **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

IT **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

LV **STERILS SASTĀVS.** Izņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

LT **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**

HU **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**

NL **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**

NO **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

PL **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

PT **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**

RO Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anestezicelor inflamabile. Produsul nu conține latex din caucluc natural.**

RU **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**

SK **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

SL **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

FI **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**

SV **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

TR Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.**

JA **内容物は滅菌済み**（パッケージが開封されていない場合）。**注意 着火源となる可能性のある物との接触を避けてください 可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません**

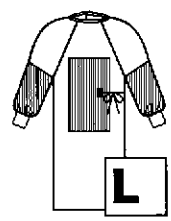
ZH **成分无菌**，除非包装被打开或损坏。**注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然胶乳**

13H

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Fabric-Reinforced Surgical Gown, Large



32
(32 x 1)

Single Use Only

REF **90112 60**

STERILE EO

LOT

Made in Honduras

(01) 3 0680651 90112 6(10) (30)32

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

135

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

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製造販売元　キンバリークラーク・ヘルスケア・インク　東京都西区みなとみらい二丁目2番1号

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

136

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Fabric-Reinforced Surgical Gown X-Large REF 90142

Fabric-Reinforced Surgical Gown X-Large REF 90142

REF 90142

Fabric-Reinforced Surgical Gown, X-Large, with Towel

OP-Kittel, gewebeverstärkt, XL, mit Handtuch

Casaque chirurgicale avec renfort en tissu, XL, avec serviette

Operatiejas van verstevigde stof, XL, met handdoek

Camice chirurgico con rinforzo in stoffa, XL, con asciugamano

Bata quirúrgica reforzada con tela, XL, con toalla

Bata cirúrgica com reforço de tecido, XL, com toalha

Stofforsterket operasjonsfrakk, XL, med håndkle

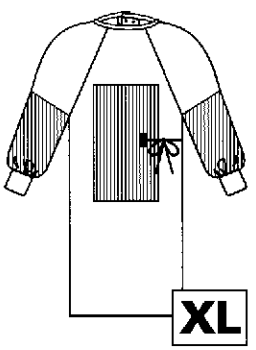
Textilförstärkt kirurgiskyddsrock, XL, med handduk

Tekstiilivahvisteinen leikkaustakki, XL, mukana käsipyyhe

Operationskittel af slidstærkt stof, XL, med håndklæde

Χειρουργική Ποδιά Ενισχυμένη με Ύφασμα, XL, με Πετσέτα

補強済サージカルガウン　XL　タオル入
滅菌済・一回限り使用
輸入・販売元・キンバリークラークPHCインターナショナルインク
横浜市西区みなとみらい 2-3-1 クイーンズタワー A



EVOLUTION® U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688; 5,188,885

LOT

Made in Honduras

91420 Rev 01

8/29/03
Form, Fill & Seal Package (primary package)

137

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sterile • Natural Rubber Latex Free

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STERILE EO

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Kimberly Clark, Roswell, GA 30076 USA. EC REP Kimberly Clark N.V., Belgicastraat 13, 1930 Zaventem, Belgium
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製造販売元：キンバリークラーク・ヘルスケア・インク　横浜市中区みなとみらい二丁目2番1号

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4/5/07
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Medium Top Web
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Prints PMS 299 Blue

138

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4/5/07
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Medium Top Web - Back (rotated 180°)
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EN CONTENTS STERILE. Unless this package is opened or damaged. CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.

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DA INDHOLDET ER STERILT med mindre pakken er åbnet eller beskadiget. ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.

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EL ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ: Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.

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LV STERILS SASTĀVS. Iznemot, ja iepakojums atvērts vai bojāts. PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.

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TR Paket açılmamış yada zarar görmemişse MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.

JP 内容物は滅菌済み（パッケージが開いていない場合）。注意：着火源となる可能性のある物との接触を避けてください 可燃性麻酔剤の近くで使用しないこと 天然ゴムラテックスは含まれていません

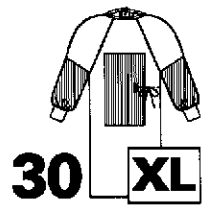
CN 成分无菌，除非包装被打开或损坏。注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然胶乳

139

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Fabric-Reinforced Surgical Gown, X-Large
OP-Kittel, gewebeverstärkt, XL
Casaque chirurgicale avec renfort en tissu, XL
Operatiejas van verstevigde stof, XL
Camice chirurgico con rinforzo in stoffa, XL
Bata quirúrgica reforzada con tela, XL
Bata cirúrgica com reforço de tecido, XL
Stofforsterket operasjonsfrakk, XL
Textilförstärkt kirurgiskyddsrock, XL
Tekstiilivahvisteinen leikkaustakki, XL
Operationskittel af slidstærkt stof, XL
Χειρουργική Ποδιά Ενισχυμένη με Ύφασμα, XL
補強済サージカルガウン　XL



LOT

Single Use Only
一回限り使用

REF **90142 50**

Made in Honduras
輸入・販売元・キンバリークラーク
PHCインターナショナルインク

滅菌済　STERILE EO

(01) 3 0680651 90142 3(10) (30)30

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

JHO

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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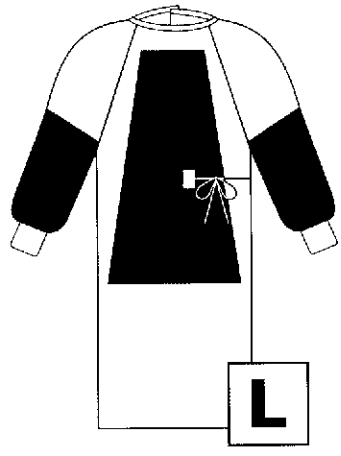
ULTRA Zoned-Impervious
Surgical Gown
Large
REF 95311

REF 95311

ULTRA Zoned-Impervious Surgical Gown, Large,

with Towel



EVOLUTION® U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,888

CE 0086

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916/6 Rev 02

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Expiration Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

142

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Cautions on Back Precautions au dos Sicherheitshinweise auf der Rückseite Виж предупрежденията на гърба Consulte las precauciones al reverso Upozornění na zadní straně Advarsler på bagsiden Hoiatused tagaküljel Προειδοποιήσεις στην πίσω πλευρά Avvertenze a tergo Piesardzības noteikumi aizmugurē Įspėjimai ant pakuotės nugarėlės Figyelmeztetések a hátoldalon Waarschuwingen op de achterkant Forsiktighetsregler finnes på baksiden Przestrogi na tyle Cuidados atrás Avertisment pe verso Меры предосторожности - на обороте Upozornenia vzadu Svarila na zadnji strani Varoitukset kääntöpuolella Försiktighetsåtgärder på baksidan Uyarılar için paketin arkasına bakınız 注意事項は裏側にあります 注意事项在背面

4/5/07
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Medium Top Web
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Prints PMS 299 Blue

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1H3

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

EN **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

FR **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu. Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

DE **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

BG **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**

ES **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**

CS **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**

DA **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**

ET **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

EL **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

IT **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

LV **STERILS SASTĀVS.** Iznemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

LT **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko lateksa.**

HU **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**

NL **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**

NO **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

PL **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

PT **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**

RO Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din cauciuc natural.**

RU **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**

SK **OBSAH JE STERILNY,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

SL **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

FI **SISÄLTÖ ON STERILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**

SV **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

TR Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI:** Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.

JA **内容物は滅菌済み**（パッケージが開けられたり破損していない限り）**注意：発火源となる可能性のある物との接触を避けてください 可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**

CH **成分无菌，除非包装被打开或损坏 注意：避免接触在燃烧源 现场有可燃麻醉剂时不要使用 无天然胶乳**

HH

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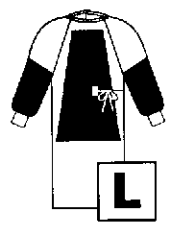
ULTRA Zoned-Impervious Surgical Gown, Large



32
(32 x 1)

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REF **95311** **25**

STERILE EO

LOT

Expiration Date

(01) 3 0680651 95311 8(10) (30)32

Made in Honduras

CE 0086

115

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1"

4/5/07
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6" x 6.75"
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Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

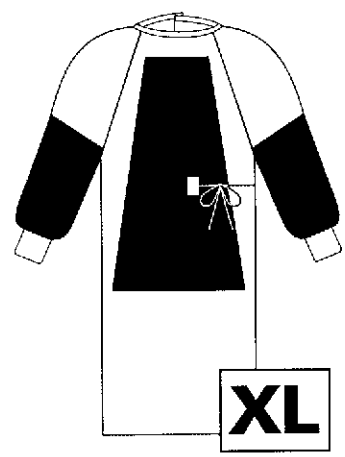
REF 95321
ULTRA Zoned-Impervious
Surgical Gown
X-Large

ULTRA Zoned-Impervious
Surgical Gown
X-Large
REF 95321

REF 95321

ULTRA Zoned-Impervious Surgical Gown, X-Large,

with Towel



EVOLUTION®

U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

CE 0086

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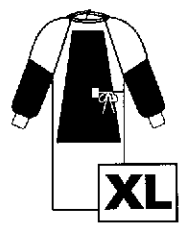
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**
(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**
(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**
(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Iznemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**
(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**
(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONŢINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezenţa anestezicelor inflamabile. Produsul nu conţine latex din caucluc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**
(JA) **内容物は滅菌済み。**包装が開封または破損していない限り。**注意:着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(CH) **成分无菌**、除非包装被打开或损坏。**注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然胶乳。**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Zoned-Impervious Surgical Gown, X-Large



30
(30 x 1)

Single Use Only

REF **95321 25**

STERILE EO

LOT

Expiration Date

Made in Honduras

(01) 3 0680651 95321 7(10) (30)30

CE 0086

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

150

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

151

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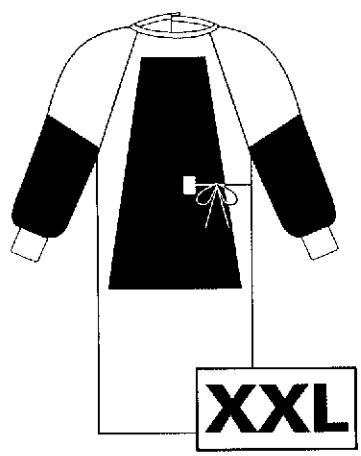
ULTRA Zoned-Impervious
Surgical Gown
XX-Large
REF 95331

ULTRA Zoned-Impervious
Surgical Gown
XX-Large
REF 95331

REF 95331

ULTRA Zoned-Impervious Surgical Gown, XX-Large,

with Towel



EVOLUTION U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

CE 0086
Made in Honduras
91678 Rev 02

LOT
Expiration Date

(01) 1 06 80651 953312

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

157

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(EN)Cautions on Back (FR)Précautions au dos (DE)Sicherheitshinweise auf der Rückseite (RU)Виж предупреждения на гърба (ES)Consulte las precauciones al reverso (SI)Upozorneni na zadnji strani (SE)Advarsler på bagsiden (HU)Hátoldalon (GR)Προειδοποιησεις στην πισω πλευρά (IT)Avvertenze a tergo (LV)Piesardzības noteikumi aizmugurē (LT)Įspėjimai ant pakuotės nugarėlės (HU)Figyelmeztetések a hátoldalon (NL)Waarschuwingen op de achterkant (NO)Forsiktigheteregler finnes på baksiden (PL)Przestrogi na tyle (PT)Cuidados atrás (PO)Avertismente pe verso (RU)Меры предосторожности - на обороте (SI)Upozornenia vzadu (SC)Svarila na zadnji strani (FI)Varoitukset käantöpuolella (SV)Forsiktighetsätgärder på baksidan (TR)Uyarılar için paketin arkasına bakınız (JA)注意事項は背面にあります (CH)注意事項在背面

4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

153

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu.Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

(DE) **STERIL**, solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**

(ES) **CONTENIDO ESTÉRIL**, a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**

(CS) **OBSAH JE STERILNÍ**, pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**

(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**

(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

(LV) **STERILS SASTĀVS.** Iznemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

(LT) **PAKUOTĖS TURINYS STERILUS**, kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**

(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**

(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**

(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**

(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din cauciuc natural.**

(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО**, если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**

(SK) **OBSAH JE STERILNY**, ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

(SI) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien läheellä. Ei sisällä luonnonkumilateksia.**

(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentielle antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**

(JA) **内容物は滅菌済み**（パッケージが開封されていない場合）。**注意：着火源となる可能性のある物との接触を避けてください 可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません**

(CH) **成分无菌。除非包装被打开或损坏。注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然胶乳。**

15H

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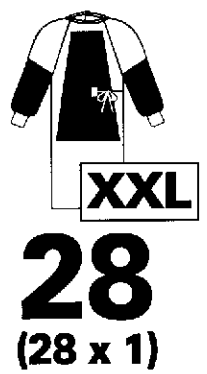
ULTRA Zoned-Impervious Surgical Gown, XX-Large



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REF 95331 25

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LOT

Expiration Date

Made in Honduras

(01) 3 0680651 95331 6(10) (30)28

CE 0086

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155

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6"

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1"

4/5/07
20-61-504-0-06
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156

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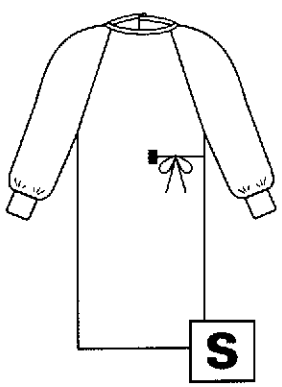
ULTRA Surgical Gown
Small
REF 90601

ULTRA Surgical Gown
Small
REF 90601

REF 90601

ULTRA Surgical Gown, Small,

with Towel



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U.S. Patent Nos.:
5,213,881; 5,271,883; 5,464,688
Other Patent Applied for

Made in Honduras

49-63-845-0-00

IDT

(01) 1 06 89651 906011

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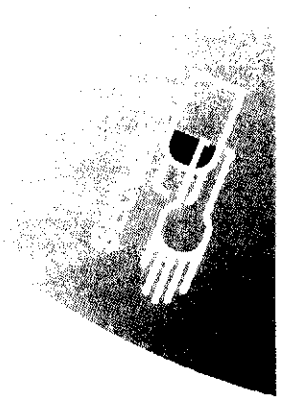

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3/16/07
10-60-213-0-02
GGI Top Web
Prints PMS 299 Blue

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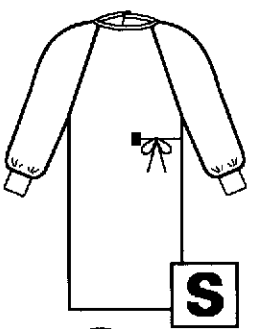
Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Surgical Gown, Small



34
(34 x 1)

Single Use Only

REF **90601** **20**

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LOT

Made in Honduras

(01) 3 0680651 90601 5(10) (30)34

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159

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6"

6.75"

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1"

4/5/07
20-62-216-0-02
6" x 6.75"
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160

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Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

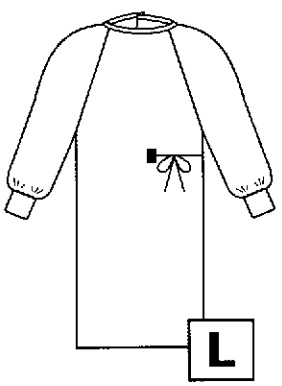
ULTRA Surgical Gown
Large
REF 90611

ULTRA Surgical Gown
Large
REF 90611

REF 90611

ULTRA Surgical Gown, Large,

with Towel



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U.S. Patent Nos.:
5,213,881; 5,271,883; 5,464,688
Other Patent Applied for
Made in Honduras
49 63 846 0-00

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161

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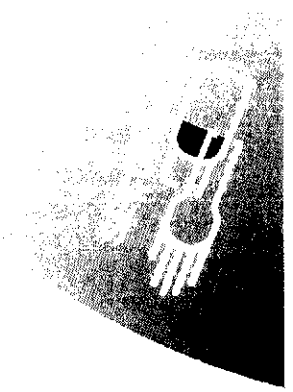

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CONTENTS STERILE. Unless this package is opened or damaged.
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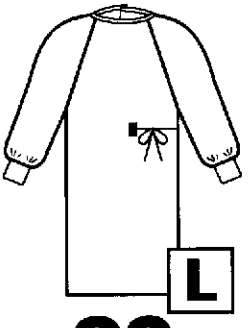
3/16/07
10-60-213-0-02
GGI Top Web
Prints PMS 299 Blue

162

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Surgical Gown, Large



32
(32 x 1)

Single Use Only

REF **90611 20**

STERILE EO

LOT

Made in Honduras

(01) 3 0680651 90611 4(10) (30)32

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

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1"

4/5/07
20-62-216-0-02
6" x 6.75"
Prints PMS 299 Blue

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164

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

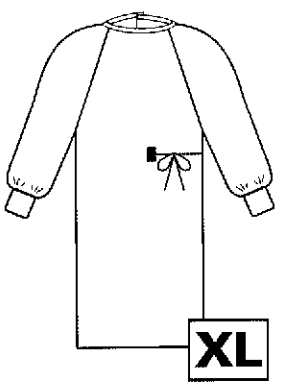
ULTRA Surgical Gown
X-Large
REF 90621

ULTRA Surgical Gown
X-Large
REF 90621

REF 90621

ULTRA Surgical Gown, X-Large,

with Towel



EVOLUTION™

U.S. Patent Nos.:
5,213,881; 5,271,883; 5,464,688
Other Patent Applied for
Made in Honduras
49-83-847-0-00

LOT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

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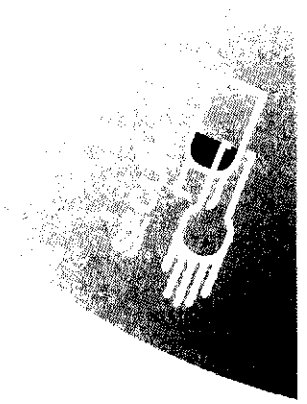

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STERILE EO

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製造販売元 キンバリー・クラーク・ヘルスケア・インク 横浜市西区みなとみらい 丁目2番1号

CONTENTS STERILE. Unless this package is opened or damaged.
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Single Use Only

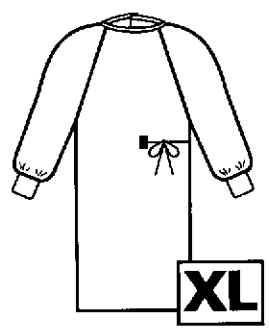
3/16/07
10-60-213-0-02
GGI Top Web
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

166

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Surgical Gown, X-Large



30
(30 x 1)

Single Use Only

REF **90621 20**

STERILE EO

Made in Honduras

LOT

(01) 3 0680651 90621 3(10) (30)30

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167

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

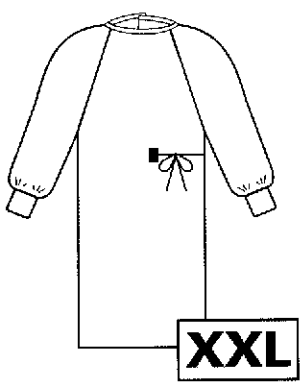
ULTRA Surgical Gown
XX-Large
REF 90631

ULTRA Surgical Gown
XX-Large
REF 90631

REF 90631

ULTRA Surgical Gown, XX-Large,

with Towel



EVOLUTION®

U.S. Patent Nos.:
5,213,881; 5,271,883; 5,464,688
Other Patent Applied for
Made in Honduras
49-63-848-0-00

LOT

(01) 1 06 68651 906318

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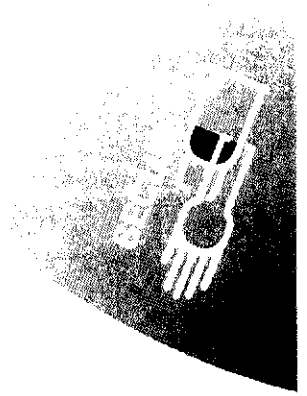
Kimberly-Clark®



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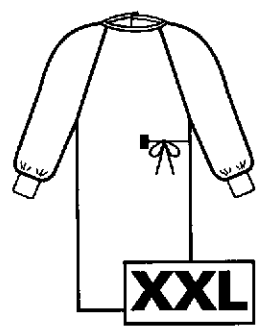
3/16/07
10-60-213-0-02
GGI Top Web
Prints PMS 299 Blue

164

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Surgical Gown, XX-Large



28
(28 x 1)

Single Use Only

REF **90631** **20**

STERILE EO

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LOT

(01) 3 0680651 90631 2(10) (30)28

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170

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

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1"

4/5/07
20-62-216-0-02
6" x 6.75"
Prints PMS 299 Blue

171

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

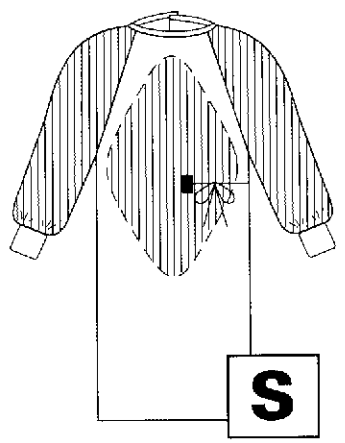
Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Fabric-Reinforced
Surgical Gown
Small
REF 95201

REF 95201

ULTRA Fabric-Reinforced Surgical Gown, Small,

with Towel



EVOLUTION®

U.S. Patent Nos.: 5,213,881; 5,271,883; 5,464,688

CE 0086

Made in Honduras

49-63-856-0-00

LOT

Expiration Date

(01) 1 06 88651 152018

ULTRA Fabric-Reinforced
Surgical Gown
Small
REF 95201

172

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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製造販売元　キンバリークラーク・ヘルスケア・インク　横浜市西区みなとみらい二丁目2番1号

Cautions on Back Précautions au dos Sicherheitshinweise auf der Rückseite Виж предупрежденията на гърба Consulte las precauciones al reverso Upozornění na zadní straně Advarsler på bagsiden Hoitafused tagakülgel Προειδοποιήσεις στην πίσω πλευρά Avvertenze a tergo Piesardzības noteikumi aizmugure Įspėjimai ant pakuotės nugarėlės Figyelmeztetések a hátoldalon Waarschuwingen op de achterkant Forsiktighetsregler finnes på baksiden Przestrogi na tyle Cuidados atrás Avertisment pe verso Меры предосторожности • на обороте Upozornenia vzadu Svarila na zadnji strani Varoitukset kääntöpuolella Försiktighetsåtgärder på baksidan Uyarılar için paketin arkasına bakınız 注意事項は背面にあります 注意事項在背面

4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

173

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu. Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**

(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**

(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**

(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**

(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

(LV) **STERILS SASTĀVS.** Iznemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Neiletot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko lateksa.**

(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyulékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**

(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**

(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**

(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din cauciuc natural.**

(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**

(SK) **OBSAH JE STERILNY,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä koskatusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**

(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.**

(JA) **内容物は滅菌済み**（パッケージが開けられていない限り）**注意 発火源となる可能性のある物との接触を避けてください 可燃性麻酔剤の近くで使用しないこと 天然ゴムラテックスは含まれていません。**

(ZH) **成分无菌，除非包装被打开或损坏 注意：避免接触在燃烧源 现场有可燃麻醉剂时不要使用 无天然胶乳。**

174

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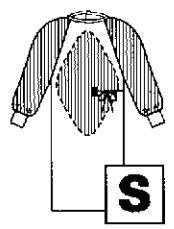
Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Fabric-Reinforced Surgical Gown, Small



30
(30 x 1)

Single Use Only

REF **95201 25**

STERILE EO

LOT

Expiration Date

Made in Honduras

(01) 3 0680651 95201 2(10) (30)30

CE 0086

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175

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

Kimberly-Clark

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

176

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Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Fabric-Reinforced
Surgical Gown
Large
REF 95211

ULTRA Fabric-Reinforced
Surgical Gown
Large
REF 95211

REF 95211

ULTRA Fabric-Reinforced Surgical Gown, Large,
with Towel

ULTRA OP-Kittel, gewebeverstärkt, L, mit Handtuch

Casaque chirurgicale ULTRA avec renfort en tissu, L, avec serviette

ULTRA operatiejas van verstevigde stof, L, met handdoek

Camice chirurgico con rinforzo in stoffa ULTRA, L, con asciugamano

Bata quirúrgica ULTRA, reforzada con tela, L, con toalla

Bata cirúrgica ULTRA com reforço de tecido, L, com toalha

ULTRA stofforsterket operasjonsfrakk, L, med håndkle

ULTRA textilförstärkt kirurgiskyddsrock, L, med handduk

ULTRA tekstiilivahvisteinen leikkaustakki, L, mukana käsipyyhe

ULTRA Operationskittel af slidstærkt stof, L, med håndklæde

Χειρουργική Ποδιά Ενισχυμένη με Ύφασμα, ULTRA, L,
με Πετσέτα

タオル入

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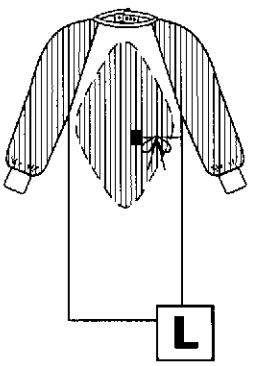
横浜市西区みなとみらい 2-3-1 クイーンズタワー A



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2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION:** Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.

(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION:** Éviter tout contact avec des sources potentielles de feu. Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.

(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT:** Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.

(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ:** Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.

(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN:** evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.

(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR:** vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.

(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL:** Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.

(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST:** Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.

(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ:** Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.

(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA:** Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.

(LV) **STERILS SASTĀVS.** Iznemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA:** Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.

(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI:** saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetikų medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.

(HU) **A TARTALMA STERIL** kíméve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY:** Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyulékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.

(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET:** Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.

(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS!** Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.

(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA:** Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.

(PT) **CONTEÚDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO:** Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.

(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT:** A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anestezicelor inflamabile. Produsul nu conține latex din cauciuc natural.

(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО:** избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.

(SK) **OBSAH JE STERILNY,** ak sa balenie neotvorí alebo nepoškodí. **POZOR:** Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.

(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO:** Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.

(FI) **SISÄLTÖ ON STERIILI.** Jos tarra pakkaus on avaamaton ja vahingoittumaton. **VAROITUS:** Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien läheltä. Ei sisällä luonnonkumilateksia.

(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG:** Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.

(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI:** Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.

(JA) **内容物は滅菌済み**（パッケージが開封されていない、または破損していない場合）。**注意：**着火源となる可燃性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。

(ZH) **成分无菌**（除非包装被打开或损坏）。**注意：**避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然橡胶

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ULTRA Fabric-Reinforced Surgical Gown, Large
ULTRA OP-Kittel, gewebeverstärkt, L
Casaque chirurgicale ULTRA avec renfort en tissu, L
ULTRA operatiejas van verstevigde stof, L
Camice chirurgico con rinforzo in stoffa ULTRA, L
Bata quirúrgica ULTRA, reforzada con tela, L
Bata cirúrgica ULTRA com reforço de tecido, L
ULTRA stofforsterket operasjonsfrakk, L
ULTRA textilförstärkt kirurgiskyddsrock, L
ULTRA tekstiilivahvisteinen leikkaustakki, L
ULTRA Operationskittel af slidstærkt stof, L LOT
Χειρουργική Ποδιά Ενισχυμένη με Ύφασμα ULTRA, L
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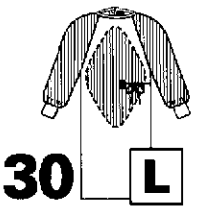

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6"

6.75"

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4/5/07
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6" x 6.75"
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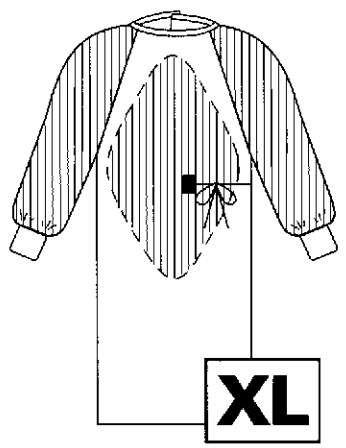
ULTRA Fabric-Reinforced
Surgical Gown
X-Large
REF 95221

ULTRA Fabric-Reinforced
Surgical Gown
X-Large
REF 95221

REF 95221

ULTRA Fabric-Reinforced Surgical Gown, X-Large,

with Towel



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5,271,883;
5,464,688

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(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION: Éviter tout contact avec des sources potentielles de feu. Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

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(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**

(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**

(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές αναφλέξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

(LV) **STERILS SASTĀVS.** Iznemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot vielā uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

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(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

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(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din cauciuc natural.**

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(SK) **OBSAH JE STERILNY,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**

(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.**

(JA) **内容物は滅菌済み**（パッケージが開いていない、または損傷していない場合）。**注意：潜在的な発火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**

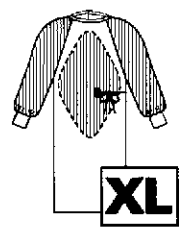
(ZH) **成分无菌**，除非包装袋打开或损坏。**注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然胶乳。**

184

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Fabric-Reinforced Surgical Gown, X-Large



28
(28 x 1)

Single Use Only

REF **95221 25**

STERILE EO

LOT

Expiration Date

Made in Honduras

(01) 3 0680651 95221 0(10) (30)28

CE 0086

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

Kimberly-Clark

Distributed in the U.S. by Kimberly-Clark Global Sales, Inc., Roswell, GA 30076 USA
In USA, please call 1-800-KCHELPS • www.kchealthcare.com
Kimberly-Clark, Roswell, GA 30076 USA; [FC]ART[]Kimberly-Clark N.V., Belgicastraat 13, 1930 Zaventem, Belgium
Sponsored in Australia by Kimberly-Clark Australia Pty Limited; 52 Alfred Street, Milsons Point, NSW 2061 • 1-800-101-071
製造販売元：キンバリークラーク・ヘルスケア・インク　極東市場ごみなとみらい　丁目2番1号

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

186

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

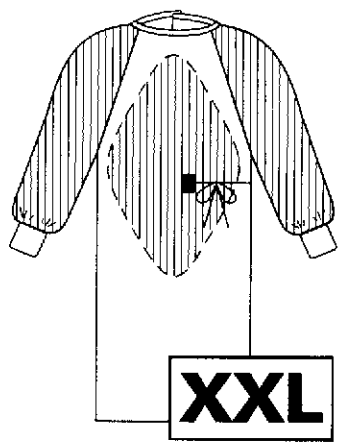
ULTRA Fabric-Reinforced
Surgical Gown
XX-Large
REF 95231

ULTRA Fabric-Reinforced
Surgical Gown
XX-Large
REF 95231

REF 95231

ULTRA Fabric-Reinforced Surgical Gown, XX-Large,

with Towel



EVOLUTION®

U.S. Patent Nos.:
5,213,881;
5,271,883;
5,464,688

CE
0086
Made in Honduras
91737 Rev 02

LOT

Expiration Date

(02) 1 06 80691 152915

6-26-07
Form, Fill & Seal Package (primary package)

137

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Kimberly-Clark*

Sterile • Natural Rubber Latex Free

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STERILE EO

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Kimberly-Clark

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In USA, please call 1-800-KCHELPS • www.kchealthcare.com
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Sponsored in Australia by Kimberly-Clark Australia Pty Limited; 52 Alfred Street, Milsons Point, NSW 2061 • 1-800-101-021
製造販売元 キンバリークラーク・ヘルスケア・インク 横浜市西区みなとみらい二丁目2番1号

Cautions on Back Précautions au dos Sicherheitshinweise auf der Rückseite Виж предупрежденията на гърба Consulte las precauciones al reverso Upozornění na zadní straně Advarsler på bagsiden Hoitatused tagaküljel Προειδοποιησεις στην πισω πλευρα Avvertenze a tergo Piesardzības noteikumi aizmugure Įspėjimai ant pakuotės nugarėlės Figyelmeztetések a hátoldalon Waarschuwingen op de achterkant Forsiktighetsregler finnes på baksiden Przestrogi na tyle Cuidados atrás Avertisment pe verso Мерки предосторожности - на обороте Upozornenia vzadu Svarila na zadnji strani Varoitukset kääntöpuolella Försiktighetsåtgärder på baksidan Uyarılar için paketin arkasına bakınız 注意事項在背面 注意事項在背面

4/5/07
10-60-204-0-03
Medium Top Web
2 x 2 Cutting Die
Prints PMS 299 Blue

188

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

CONTENTS STERILE. Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**

STÉRILE. Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION: Éviter tout contact avec des sources potentielles de feu. Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**

STERIL, solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**

СЪДЪРЖАНИЕТО Е СТЕРИЛНО ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**

CONTENIDO ESTÉRIL, a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**

OBSAH JE STERILNÍ, pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**

INDHOLDET ER STERILT med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**

STERIILNE välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**

ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ: Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**

CONTENUTO STERILE. Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**

STERILS SASTĀVS. Izņemot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**

PAKUOTĖS TURINYS STERILUS, kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko lateksa.**

A TARTALMA STERIL kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**

INHOUD STERIEL. Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**

STERILT INNHOLD. Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**

MATERIAŁ WYJAŁOWIONY. O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**

CONTEÚDO ESTERILIZADO. Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**

Acest pachet are un CONȚINUT STERIL dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anesteziceior inflamabile. Produsul nu conține latex din cauciuc natural.**

СОДЕРЖИМОЕ СТЕРИЛЬНО, если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**

OBSAH JE STERILNY, ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**

VSEBINA STERILNA. Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**

SISÄLTÖ ON STERIILI. Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien läheltä. Ei sisällä luonnonkumilateksia.**

INNEHÅLLET STERILT. Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**

Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks içermez.**

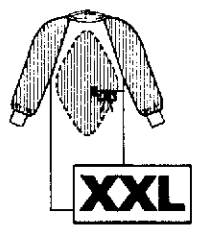
内容物は滅菌済み。[illegible] 注意: 着火源となる可燃性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。

成分无菌，除非包装被打开或损坏。注意：避免接触在燃烧源。现场有可燃麻醉剂时不要使用。无天然橡胶乳

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

ULTRA Fabric-Reinforced Surgical Gown, XX-Large



28
(28 x 1)

Single Use Only

REF **95231 25**

STERILE EO

LOT

Expiration Date

Made in Honduras

(01) 3 0680651 95231 9(10) (30)28

CE 0086

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

190

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

Kimberly-Clark

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In USA, please call 1-800-KCHELPS • www.kchealthcare.com
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Sponsored in Australia by Kimberly-Clark Australia Pty Limited; 52 Alfred Street, Milsons Point, NSW 2061 • 1-800-101-021
製造販売元：キンバリークラーク・ヘルスケア・インク　東京都西区みなとみらい　丁目2番1号

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1"

4/5/07
20-61-504-0-06
6" x 6.75"
Prints PMS 299 Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

APPENDIX III

Copies of current promotional material used to market surgical gowns cleared for market under K781682, K842115 and K861600.

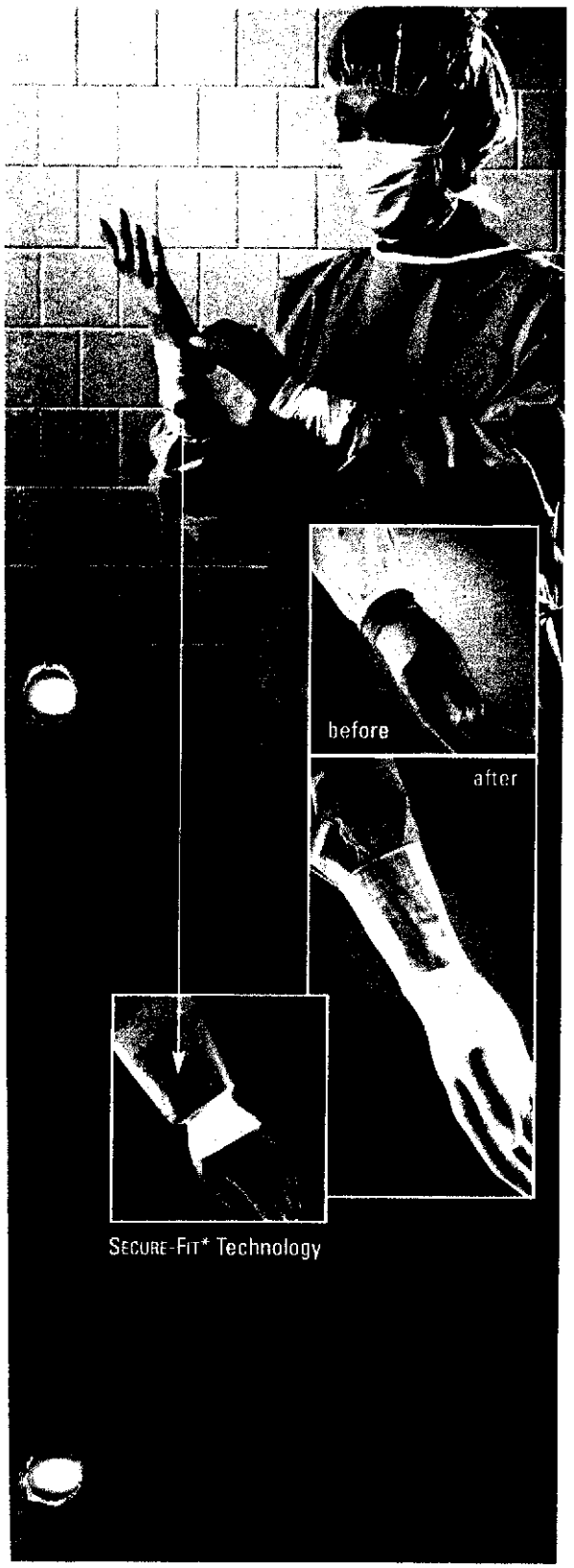
Note: The promotional material attached also contains references to our MicroCool Surgical Gown product line that is cleared under a separate 510(k) which is not part of this submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

KIMBERLY-CLARK* ULTRA AND MICROCOOL* Surgical Gowns

Note: The MicroCool Surgical Gown is cleared under a separate 510(K) not part of this submission.



Introducing a new technology that helps surgical gloves stay in place.

New SECURE-FIT* Technology on KIMBERLY-CLARK* Surgical Gowns.

Have you ever been concerned about cross-contamination during surgery due to glove slip-down—or even had to stop a procedure, re-scrub and re-gown because of it? Then you know what a relief it would be to have your gloves stay securely in place. Well, that relief has arrived.

Kimberly-Clark is proud to introduce a breakthrough in healthcare protection technology. Our ULTRA Non-Reinforced Surgical Gowns and MICROCOOL* Surgical Gowns now feature SECURE-FIT*—a unique, proprietary technology, shown to reduce the amount of surgical glove slipdown when used with market leading surgical gloves. You can see the SECURE-FIT* coating on the forearm of each sleeve, keeping your gloves in place and keeping you confident that both you and your patient are protected.

When you think Kimberly-Clark gowns with SECURE-FIT* Technology, think MICROCOOL* and ULTRA.

Now you can enjoy the peace of mind that comes with SECURE-FIT* technology on a new line of ULTRA and MICROCOOL* Surgical Gowns without changing your current practice of surgical glove donning.

You have a lot of things to worry about during a procedure; pulling up your surgical gloves shouldn't be one of them. SECURE-FIT* technology on MICROCOOL* and ULTRA Non-Reinforced Surgical Gowns is just one more reason to depend on Kimberly-Clark, for trusted clinical solutions that help keep you and your patients safe—and help keep your focus where it belongs.

The KIMBERLY-CLARK* Surgical Gowns with SECURE-FIT* technology are just some of the clinical solutions that you can depend on to meet the demands of your fast-paced world.

Whether your needs involve preventing healthcare-associated infections, surgical and digestive solutions or pain management, with Kimberly-Clark you'll always have one less worry.

Kimberly-Clark

*Trusted Clinical Solutions**

193

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Look for the SECURE-FIT* icon on select KIMBERLY-CLARK* ULTRA and MICROCOOL* gowns for added confidence and barrier protection.

KIMBERLY-CLARK* ULTRA Non-Reinforced Surgical Gowns with SECURE-FIT*

- 4th Generation SMS Fabric
- Low Linting Fabric
- Raglan Sleeves with SECURE-FIT* Technology
- Color Coded Neck Binding

Code	Description	Packaging
90601	Sterile, Small	Items/Case = 34
90611	Sterile, Large	Items/Case = 32
70611	Non-Sterile, Large	Items/Case = 42
90621	Sterile, X-Large	Items/Case = 30
70621	Non-Sterile, X-Large	Items/Case = 40
90631	Sterile, XX-Large	Items/Case = 28
70631	Non-Sterile, XX-Large	Items/Case = 36

KIMBERLY-CLARK* MICROCOOL* Surgical Gowns with SECURE-FIT*

- Breathable Impervious fabric – Passes ASTM 1671
- Raglan Sleeves with SECURE-FIT* Technology
- Color Coded Neck Binding

Code	Description	Packaging
92339	Sterile, Large	Items/Case = 30
72339	Non-Sterile, Large	Items/Case = 40
92343	Sterile, X-Large	Items/Case = 28
72343	Non-Sterile, X-Large	Items/Case = 38
92346	Sterile, XX-Large	Items/Case = 26
72346	Non-Sterile, XX-Large	Items/Case = 36
92349	Specialty Gown, Sterile, Large	Items/Case = 28
72349	Specialty Gown, Non-Sterile, Large	Items/Case = 40
92352	Specialty Gown, Sterile, X-Large	Items/Case = 26
72352	Specialty Gown, Non-Sterile, X-Large	Items/Case = 38
92356	Specialty Gown, Sterile, XX-Large	Items/Case = 26
72356	Specialty Gown, Non-Sterile, XX-Large	Items/Case = 36

All codes in **bold** indicate a sterile product.

Commitment to Excellence

If, for any reason, our products do not meet your expectations, please let us know your comments or suggestions for improvement. Your input will result in a concerted effort on our part to meet your requirements. Our goal is to provide quality products that completely meet your needs time after time.

For more information, please call 1-800-KCHELPS in the United States, ask your sales representative, or visit our web site at www.kchealthcare.com.

† Sample includes Regent Biogel, Ansell-Perry, Semper-Med Surgical Gloves

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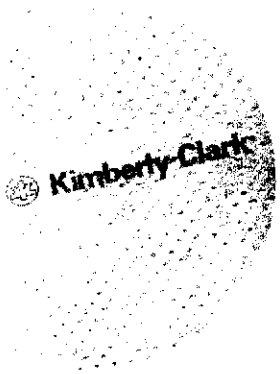
KLM-1066 H8467

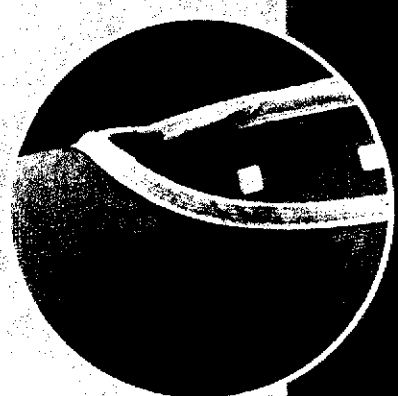
Trusted Clinical Solutions

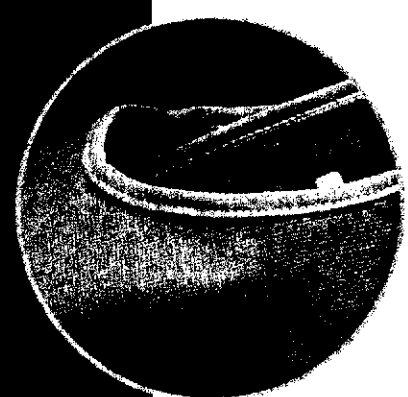
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

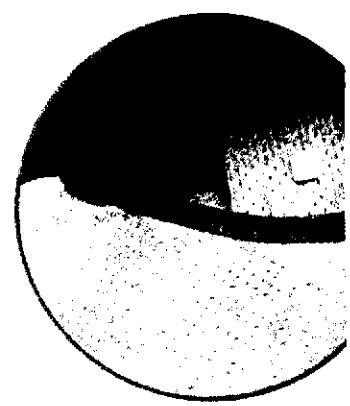
Records processed under FOIA Request # 2015-9647, Released by CDRH on 05-28-2016

Introducing the KIMBERLY-CLARK* Color-Key for Instant Gown Recognition









Kimberly-Clark

Questions? Contact FDA/CDRH/OCE/DID at CDRH-CISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Now Choosing the Right Gown Is Easier than Ever.

At Kimberly-Clark, we understand how much is on your mind as you prepare for a medical procedure. One thing you shouldn't have to worry about is selecting the right gown. According to a recent Kimberly-Clark survey of caregivers, almost half (47%) have — or know someone who has — selected the wrong gown type, exposing staff and patients to safety risks such as inadequate protection from strikethrough and compromising the sterile field.

That's why we've created the KIMBERLY-CLARK* Color-Key—neckbands that are color-keyed within our three surgical gown lines. Now you can instantly recognize which KIMBERLY-CLARK* gown to choose for the level of protection you need:

Impervious, for lengthy, fluid-intensive procedures

Green Fabric-Reinforced, for moderate to high fluid contact

Yellow Non-Reinforced, for low to moderate fluid contact

Also, our color key makes it easy to track the number of different types of gowns that are frequently used. So inventory management is simplified and waste resulting from the overstocking of rarely used gowns is reduced.

To be sure you're getting the ultimate in comfort and protection, look for the name Kimberly-Clark on all your surgical gowns. And look for the colored neckband to tell at a glance you have precisely the gown you need.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Note: The MicroCool Surgical Gown is cleared under a separate 510(K) not part of this submission.

KIMBERLY-CLARK* MICROCOOL* Breathable Impervious Surgical Gowns

The market leading breathable impervious surgical gown, MICROCOOL* provides our highest level of protection against blood and bodily fluids and keeps the wearer cool and comfortable during even the longest procedures. Look for the red neckband on all MICROCOOL* Gowns.

- Breathable, clothlike fabric for coolness and comfort
- Offers consistently reliable impervious protection in the OR
- Meets both ASTM F1670 and ASTM F1671 standards for resistance of materials used in protective clothing
- A cost-competitive solution to standardize your gown mix

KIMBERLY-CLARK* ULTRA Surgical Gowns

ULTRA Surgical Gowns are designed to provide the right balance of comfort and protection for the widest range of procedures. From non-reinforced to impervious, there are five different gown types, all made with enhanced ULTRA SMS fabric.

- Non-Reinforced ULTRA Surgical Gowns for procedures with low to moderate fluid contact. Look for the yellow neckband.
- ULTRA Fabric-Reinforced Surgical Gowns offer additional fabric in key areas, for procedures with moderate fluid exposure. Look for the green neckband.
- ULTRA Zoned-Impervious Gowns and Impervious Gowns have plastic-reinforced protection in critical areas, for procedures involving greater fluid, duration, and pressure. Look for the red neckband.
- ULTRA Specialty Gowns have an extra-long, A-line design, with full-length impervious front panel and forearm areas for extra protection in a sitting position. Look for the red neckband.

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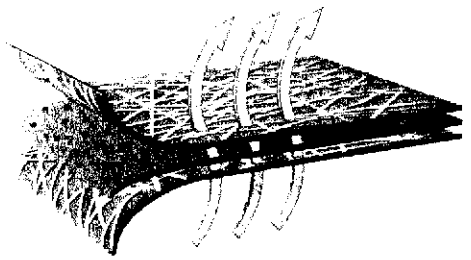
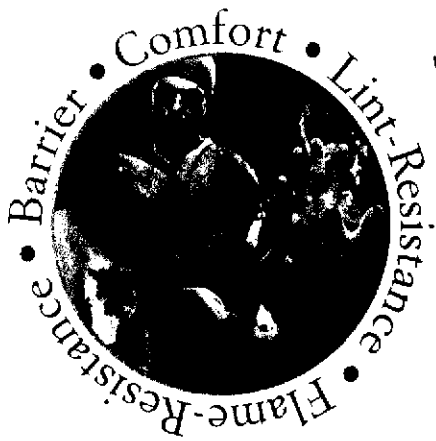


MicroCool* Surgical Gowns are made with Kimberly-Clark's advanced microporous fabric technology. Two soft layers of nonwoven fabric enclose a thin yet strong layer of breathable film. The result is impervious protection from contact with blood and bodily fluids. Yet, the film layer permits moisture vapor to pass easily through the gown, dispelling heat and keeping the wearer cool and comfortable.



When choosing gowns and drapes for your facility, it is important to weigh all of the factors that impact gown or drape performance, as defined by AORN in its 2004 Standards, Recommended Practices and Guidelines[4].

Note: The MicroCool Surgical Gown is cleared under a separate 510(K) not part of this submission.

Kimberly-Clark* Evolution* 4 Surgical Gowns

Evolution* 4 Non-Reinforced Surgical Gowns, our trusted standard SMS gowns, are extremely comfortable and provide the right level of protection for shorter, less fluid-intensive procedures. Look for the yellow neckband on all Evolution* 4 Non-Reinforced Gowns.

Evolution* 4 is also available in a fabric-reinforced gown, for procedures with more moderate fluid exposure.

Evolution* 4 Gowns, like all Kimberly-Clark* Surgical Gowns, are designed to meet the AORN 2004 Standards for surgical gowns. They are:

- Resistant to strikethrough by blood and other bodily fluids
- Low-linting and abrasion resistant
- Flame-resistant
- Comfortable

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KIMBERLY-CLARK* MICROCOOL* Gowns

Breathable Impervious Surgical Gowns

KIMBERLY-CLARK* ULTRA Gowns

Impervious Gowns

Zoned-Impervious Gowns

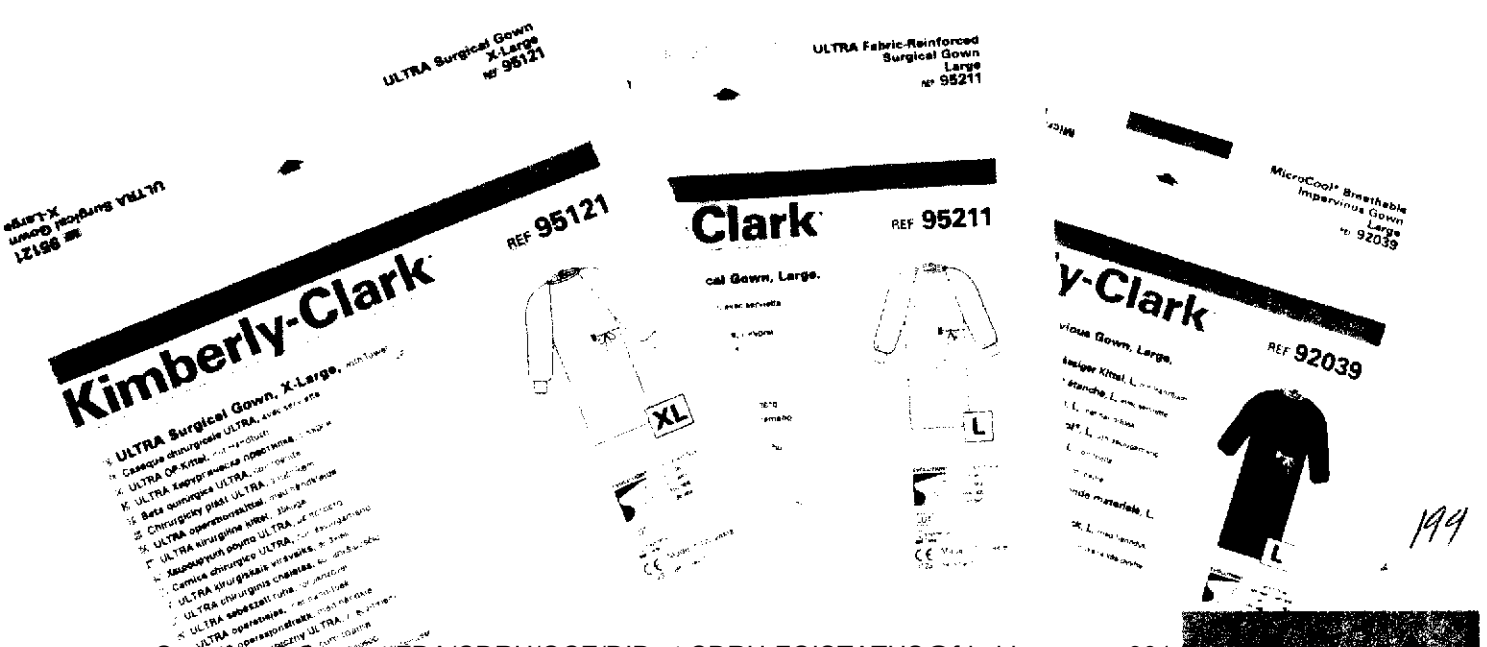
Fabric-Reinforced Surgical Gowns

Non-Reinforced Surgical Gowns

KIMBERLY-CLARK* EVOLUTION* 4 Gowns

Fabric-Reinforced Surgical Gowns

Non-Reinforced Surgical Gowns



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A Request # 2015-9647; Released by CDRH on 03-28-2016

Kimberly-Clark offers a wide array of healthcare products designed for patient and staff protection.

Products for the Operating Room:

Cardiac Multifunction Electrodes
Closed Suction Systems
Enteral Feeding Tubes
Facial Protection
Gastrointestinal Endoscopy
Medical Gloves
Pain Management
Protective Apparel
Sterilization Packaging
Surgical Accessories
Surgical Drapes & Packs
Surgical Gowns
Temperature Management
Temperature Therapy

Other Healthcare Products:

Diagnostics
Gastric Lavage
Health Care Skin Wellness
Oral Care
Patient Care

Commitment to Excellence

If, for any reason, our products do not meet your expectations, please let us know your comments or suggestions for improvement. Your input will result in a concerted effort on our part to meet your requirements. Our goal is to provide quality products that completely meet your needs time after time.

For more information, please call 1-800-KCHELPS in the United States, or visit our web site at www.kchealthcare.com.

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[b]The Association of periOperative Registered Nurses, 2004 Standards, Recommended Practices and Guidelines.

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APPENDIX IV

Copy of the Kimberly-Clark Health Care **US** website surgical gown promotional material (http://www.kchealthcare.com) currently being used to market all surgical gowns cleared under K781682, K842115, and K861600.

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ULTRA

- **ULTRA Surgical Gowns**
- **ULTRA Fabric-Reinforced Surgical Gowns**
- **ULTRA Zoned-Impervious Surgical Gowns**
- **ULTRA Impervious Surgical Gowns**
- **ULTRA Specialty Impervious Gowns**

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ULTRA Surgical Gowns

- **ULTRA Non-Reinforced Surgical Gowns**
- **ULTRA* Non-Reinforced SECURE-FIT* Tech.**

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ULTRA Non-Reinforced Surgical Gowns

Back to ULTRA Surgical Gowns

Currently displaying products 1-6 of 11

Page 1 of 2 Next

Stock #	Description
95101	ULTRA SURGICAL GOWN, STERILE, SMALL
71301	ULTRA SURGICAL GOWN, NON-STERILE, SMALL
95111	ULTRA SURGICAL GOWN, STERILE, LARGE
95055	ULTRA SURGICAL GOWN, STERILE, LARGE, 2-PACK
71311	ULTRA SURGICAL GOWN, NON-STERILE, LARGE
74115	ULTRA SURGICAL GOWN, NON-STERILE, LARGE, HANDI-BIN

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ULTRA Non-Reinforced Surgical Gowns

Back to ULTRA Surgical Gowns

Currently displaying products 7-11 of 11

Page 2 of 2 Previous

Stock #	Description
95121	ULTRA SURGICAL GOWN, STERILE, X-LARGE
71321	ULTRA SURGICAL GOWN, NON-STERILE, X-LARGE
74116	ULTRA SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN
95131	ULTRA SURGICAL GOWN, STERILE, XX-LARG
71331	ULTRA SURGICAL GOWN, NON-STERILE, XX-LARGE

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ULTRA Non-Reinforced Surgical Gowns

ULTRA SURGICAL GOWN, STERILE, SMALL

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

Detail Chart

Stock #	Description	Packaging
95101	ULTRA SURGICAL GOWN, STERILE, SMALL	Case more

Back

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ULTRA Non-Reinforced Surgical Gowns

ULTRA SURGICAL GOWN, NON-STERILE, SMALL

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- GENEROUS CUT
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
71301	ULTRA SURGICAL GOWN, NON-STERILE, SMALL	Case more

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ULTRA Non-Reinforced Surgical Gowns

ULTRA SURGICAL GOWN, STERILE, LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

Detail Chart

Stock #	Description	Packaging
95111	ULTRA SURGICAL GOWN, STERILE, LARGE	Case more

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ULTRA Non-Reinforced Surgical Gowns

ULTRA SURGICAL GOWN, STERILE, LARGE, 2-PACK

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

Detail Chart

Stock #	Description	Packaging
95055	ULTRA SURGICAL GOWN, STERILE, LARGE, 2-PACK	Case more

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ULTRA Non-Reinforced Surgical Gowns

ULTRA SURGICAL GOWN, NON-STERILE, LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING,YELLOW
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

Detail Chart

Stock #	Description	Packaging
71311	ULTRA SURGICAL GOWN, NON-STERILE, LARGE	Case more

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ULTRA Non-Reinforced Surgical Gowns

ULTRA SURGICAL GOWN, STERILE, X-LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

Detail Chart

Stock #	Description	Packaging
95121	ULTRA SURGICAL GOWN, STERILE, X-LARGE	Case more

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ULTRA Non-Reinforced Surgical Gowns

ULTRA SURGICAL GOWN, NON-STERILE, X-LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
71321	ULTRA SURGICAL GOWN, NON-STERILE, X-LARGE	Case more

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ULTRA Non-Reinforced Surgical Gowns

ULTRA SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
74116	ULTRA SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN	Case more

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ULTRA Non-Reinforced Surgical Gowns

ULTRA SURGICAL GOWN, STERILE, XX-LARG

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
95131	ULTRA SURGICAL GOWN, STERILE, XX-LARG	Case more

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ULTRA Non-Reinforced Surgical Gowns

ULTRA SURGICAL GOWN, NON-STERILE, XX-LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING,YELLOW
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
71331	ULTRA SURGICAL GOWN, NON-STERILE, XX-LARGE	Case more

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ULTRA* Non-Reinforced SECURE-FIT* Tech.

Back to ULTRA Surgical Gowns

Currently displaying products 1-6 of 7

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Stock #	Description
90601	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, SMALL
90611	KIMBERLY-CLARK* ULTRA SURGICAL GOWN, STERILE, LARGE
70811	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, LARGE
90621	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, X-LARGE
70821	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, X-LARGE
90631	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, XX-LARGE

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ULTRA* Non-Reinforced SECURE-FIT* Tech.

ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, SMALL

Features:

- SECURE-FIT* ANTI-SLIP TECHNOLOGY
- GENEROUS CUT & ADDED LENGTH
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
90601	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, SMALL	Case more

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ULTRA* Non-Reinforced SECURE-FIT* Tech.

KIMBERLY-CLARK* ULTRA SURGICAL GOWN, STERILE, LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- LOW LINTING FABRIC
- RAGLAN SLEEVES WITH SECURE-FIT* TECHNOLOGY
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- BOOK FOLD

LATEX-FREE STERILE

Detail Chart

Stock #	Description	Packaging
90611	KIMBERLY-CLARK* ULTRA SURGICAL GOWN, STERILE, LARGE	Case more

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ULTRA* Non-Reinforced SECURE-FIT* Tech.

ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, LARGE

Features:

- SECURE-FIT* ANTI-SLIP TECHNOLOGY
- GENEROUS CUT & ADDED LENGTH
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
70811	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, LARGE	Case more

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ULTRA* Non-Reinforced SECURE-FIT* Tech.

ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, X-LARGE

Features:

- SECURE-FIT* ANTI-SLIP TECHNOLOGY
- GENEROUS CUT & ADDED LENGTH
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- BOOK FOLD

LATEX-FREE STERILE

Detail Chart

Stock #	Description	Packaging
90621	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, X-LARGE	Case more

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ULTRA* Non-Reinforced SECURE-FIT* Tech.

ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, X-LARGE

Features:

- SECURE-FIT* ANTI-SLIP TECHNOLOGY
- GENEROUS CUT & ADDED LENGTH
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
70821	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, X-LARGE	Case more

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ULTRA* Non-Reinforced SECURE-FIT* Tech.

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Stock #	Description
70631	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, XX-LARGE

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ULTRA* Non-Reinforced SECURE-FIT* Tech.

ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, XX-LARGE

Features:

- SECURE-FIT* ANTI-SLIP TECHNOLOGY
- GENEROUS CUT & ADDED LENGTH
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- BOOK FOLD

NON-STERILE

Detail Chart

Stock #	Description	Packaging
70631	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, XX-LARGE	Case more

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ULTRA Fabric-Reinforced Surgical Gowns

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Stock #	Description
95201	ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, SMALL
95211	ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, LARGE
74911	ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE
79511	ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE, HANDI-BIN
95221	ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, X-LARGE
74921	ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE

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ULTRA Fabric-Reinforced Surgical Gowns

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Stock #	Description
79512	ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN
95231	ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, XX-LARGE
74931	ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, XX-LARGE

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ULTRA Fabric-Reinforced Surgical Gowns

ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, SMALL

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- EXTRA WIDE FABRIC REINFORCEMENTS
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING, GREEN
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
95201	ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, SMALL	Case more

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ULTRA Fabric-Reinforced Surgical Gowns

ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- EXTRA WIDE FABRIC REINFORCEMENTS
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- BOOK FOLD

LATEX FREE STERILE

Detail Chart

Stock #	Description	Packaging
95211	ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, LARGE	Case more

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ULTRA Fabric-Reinforced Surgical Gowns

ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- EXTRA WIDE FABRIC REINFORCEMENTS
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING,GREEN
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
74911	ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE	Case more

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ULTRA Fabric-Reinforced Surgical Gowns

ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE, HANDI-BIN

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- EXTRA WIDE FABRIC REINFORCEMENTS
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
79511	ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE, HANDI-BIN	Case more

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ULTRA Fabric-Reinforced Surgical Gowns

ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, X-LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- EXTRA WIDE FABRIC REINFORCEMENTS
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING, GREEN
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
95221	ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, X-LARGE	Case more

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ULTRA Fabric-Reinforced Surgical Gowns

ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- EXTRA WIDE FABRIC REINFORCEMENTS
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING, GREEN
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
74921	ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE	Case more

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ULTRA Fabric-Reinforced Surgical Gowns

ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- EXTRA WIDE FABRIC REINFORCEMENTS
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING, GREEN
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
79512	ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN	Case more

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ULTRA Fabric-Reinforced Surgical Gowns

ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, XX-LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- EXTRA WIDE FABRIC REINFORCEMENTS
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- BOOK FOLD

LATEX FREE STERILE CE

Detail Chart

Stock #	Description	Packaging
95231	ULTRA FABRIC-REINFORCED SURGICAL GOWN, STERILE, XX-LARGE	Case more

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ULTRA Fabric-Reinforced Surgical Gowns

ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, XX-LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- EXTRA WIDE FABRIC REINFORCEMENTS
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING, GREEN
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
74931	ULTRA FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, XX-LARGE	Case more

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ULTRA Fabric-Reinforced Surgical Gowns

- **ULTRA Surgical Gowns**
- **ULTRA Fabric-Reinforced Surgical Gowns**
- **ULTRA Zoned-Impervious Surgical Gowns**
- **ULTRA Impervious Surgical Gowns**
- **ULTRA Specialty Impervious Gowns**

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ULTRA Zoned-Impervious Surgical Gowns

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95311	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, STERILE, LARGE
72311	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, LARGE
79611	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, LARGE, HANDI-BIN
95321	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, STERILE, X-LARGE
79312	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN
95331	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, STERILE, XX-LARGE

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ULTRA Zoned-Impervious Surgical Gowns

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Stock #	Description
72331	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, XX-LARGE

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ULTRA Zoned-Impervious Surgical Gowns

ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, STERILE, LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- PLASTIC-REINFORCED FRONT PANEL AND SLEEVES - PASSES ASTM F1671
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- GENEROUS CUT
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
95311	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, STERILE, LARGE	Case more

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ULTRA Zoned-Impervious Surgical Gowns

ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- PLASTIC-REINFORCED FRONT PANEL AND SLEEVES # PASSES ASTM F1671
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- GENEROUS CUT
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
72311	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, LARGE	Case more

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ULTRA Zoned-Impervious Surgical Gowns

ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, LARGE, HANDI-BIN

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- PLASTIC-REINFORCED FRONT PANEL & SLEEVES
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING,RED
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
79611	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, LARGE, HANDI-BIN	Case more

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ULTRA Zoned-Impervious Surgical Gowns

ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, STERILE, X-LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- PLASTIC-REINFORCED FRONT PANEL & SLEEVES
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING,RED
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

Natural LATEX-FREE STERILE CE

Detail Chart

Stock #	Description	Packaging
95321	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, STERILE, X-LARGE	Case more

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ULTRA Zoned-Impervious Surgical Gowns

ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- PLASTIC-REINFORCED FRONT PANEL & SLEEVES
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, RED
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

Natural LATEX FREE NON STERILE CE

Detail Chart

Stock #	Description	Packaging
79312	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN	Case more

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ULTRA Zoned-Impervious Surgical Gowns

ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, STERILE, XX-LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- PLASTIC-REINFORCED FRONT PANEL & SLEEVES
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, RED
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- GENEROUS CUT
- BOOK FOLD

LATEX FREE STERILE CE

Detail Chart

Stock #	Description	Packaging
95331	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, STERILE, XX-LARGE	Case more

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ULTRA Zoned-Impervious Surgical Gowns

ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, XX-LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- PLASTIC-REINFORCED FRONT PANEL AND SLEEVES - PASSES ASTM F1671
- LOW LINTING FABRIC
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- GENEROUS CUT
- BOOK FOLD

Natural LATEX FREE NON STERILE CE

Detail Chart

Stock #	Description	Packaging
72331	ULTRA ZONED-IMPERVIOUS SURGICAL GOWN, NON-STERILE, XX-LARGE	Case more

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2HH

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ULTRA Impervious Surgical Gowns

- **ULTRA Surgical Gowns**
- **ULTRA Fabric-Reinforced Surgical Gowns**
- **ULTRA Zoned-Impervious Surgical Gowns**
- **ULTRA Impervious Surgical Gowns**
- **ULTRA Specialty Impervious Gowns**

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ULTRA Impervious Surgical Gowns

Back to ULTRA

Stock #	Description
95411	ULTRA IMPERVIOUS SURGICAL GOWN, STERILE, LARGE
74411	ULTRA IMPERVIOUS SURGICAL GOWN, NON-STERILE, LARGE
95421	ULTRA IMPERVIOUS SURGICAL GOWN, STERILE, X-LARGE
74421	ULTRA IMPERVIOUS SURGICAL GOWN, NON-STERILE, X-LARGE
95431	ULTRA IMPERVIOUS SURGICAL GOWN, STERILE, XX-LARGE

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ULTRA Impervious Surgical Gowns

ULTRA IMPERVIOUS SURGICAL GOWN, STERILE, LARGE

Features:

- PASSES ASTM1671
- PROPRIETARY 4TH GENERATION SMS FABRIC
- FULL-LENGTH IMPERVIOUS FRONT PANEL & FOREARMS
- RAGLAN SLEEVES
- BOOK FOLD
- GENEROUS CUT

LATEX-FREE STERILE CE

Detail Chart

Stock #	Description	Packaging
95411	ULTRA IMPERVIOUS SURGICAL GOWN, STERILE, LARGE	Case more

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ULTRA Impervious Surgical Gowns

ULTRA IMPERVIOUS SURGICAL GOWN, NON-STERILE, LARGE

Features:

- PASSES ASTM1671
- PROPRIETARY 4TH GENERATION SMS FABRIC
- FULL-LENGTH IMPERVIOUS FRONT PANEL & FOREARMS
- RAGLAN SLEEVES
- BOOK FOLD
- GENEROUS CUT

LATEX-FREE NON STERILE

Detail Chart

Stock #	Description	Packaging
74411	ULTRA IMPERVIOUS SURGICAL GOWN, NON-STERILE, LARGE	Case more

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ULTRA Impervious Surgical Gowns

ULTRA IMPERVIOUS SURGICAL GOWN, STERILE, X-LARGE

Features:

- PASSES ASTM1671
- PROPRIETARY 4TH GENERATION SMS FABRIC
- FULL-LENGTH IMPERVIOUS FRONT PANEL & FOREARMS
- RAGLAN SLEEVES
- BOOK FOLD
- GENEROUS CUT

Non-LATEX FREE STERILE CE

Detail Chart

Stock #	Description	Packaging
95421	ULTRA IMPERVIOUS SURGICAL GOWN, STERILE, X-LARGE	Case more

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ULTRA Impervious Surgical Gowns

ULTRA IMPERVIOUS SURGICAL GOWN, NON-STERILE, X-LARGE

Features:

- PASSES ASTM1671
- PROPRIETARY 4TH GENERATION SMS FABRIC
- FULL-LENGTH IMPERVIOUS FRONT PANEL & FOREARMS
- RAGLAN SLEEVES
- BOOK FOLD
- GENEROUS CUT

NON STERILE

Detail Chart

Stock #	Description	Packaging
74421	ULTRA IMPERVIOUS SURGICAL GOWN, NON-STERILE, X-LARGE	Case more

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ULTRA Impervious Surgical Gowns

ULTRA IMPERVIOUS SURGICAL GOWN, STERILE, XX-LARGE

Features:

- PASSES ASTM1671
- PROPRIETARY 4TH GENERATION SMS FABRIC
- FULL-LENGTH IMPERVIOUS FRONT PANEL & FOREARMS
- RAGLAN SLEEVES
- BOOK FOLD
- GENEROUS CUT

Natural LATEX-FREE STERILE CE

Detail Chart

Stock #	Description	Packaging
95431	ULTRA IMPERVIOUS SURGICAL GOWN, STERILE, XX-LARGE	Case more

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ULTRA Impervious Surgical Gowns

- **ULTRA Surgical Gowns**
- **ULTRA Fabric-Reinforced Surgical Gowns**
- **ULTRA Zoned-Impervious Surgical Gowns**
- **ULTRA Impervious Surgical Gowns**
- **ULTRA Specialty Impervious Gowns**

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ULTRA Specialty Impervious Gowns

Back to ULTRA

Stock #	Description
95511	ULTRA SPECIALTY GOWN, STERILE, LARGE
76511	ULTRA SPECIALTY GOWN, NON-STERILE, LARGE
95521	ULTRA SPECIALTY GOWN, STERILE, X-LARGE
76521	ULTRA SPECIALTY GOWN, NON-STERILE, X-LARGE
95531	ULTRA SPECIALTY GOWN, STERILE, XX-LARGE

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ULTRA Specialty Impervious Gowns

ULTRA SPECIALTY GOWN, STERILE, LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- FULL-LENGTH IMPERVIOUS FRONT PANEL AND FOREARMS
- PATENTED A-LINE DESIGN FOR SEATED PROCEDURES
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
95511	ULTRA SPECIALTY GOWN, STERILE, LARGE	Case more

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ULTRA Specialty Impervious Gowns

ULTRA SPECIALTY GOWN, NON-STERILE, LARGE

Features:

- PROPRIETARY 4TH GENERATION SMS FABRIC
- FULL-LENGTH IMPERVIOUS FRONT PANEL AND FOREARMS
- PATENTED A-LINE DESIGN FOR SEATED PROCEDURES
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- BOOK FOLD

LATEX FREE NON STERILE

Detail Chart

Stock #	Description	Packaging
76511	ULTRA SPECIALTY GOWN, NON-STERILE, LARGE	Case more

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ULTRA Specialty Impervious Gowns

ULTRA SPECIALTY GOWN, STERILE, X-LARGE

Features:

- PASSES ASTM1671
- PROPRIETARY 4TH GENERATION SMS FABRIC
- FULL-LENGTH IMPERVIOUS FRONT PANEL & FOREARMS
- PATENTED A-LINE DESIGN FOR SEATED PROCEDURES
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, RED
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- BOOK FOLD

LATEX-FREE STERILE CE

Detail Chart

Stock #	Description	Packaging
95521	ULTRA SPECIALTY GOWN, STERILE, X-LARGE	Case more

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ULTRA Specialty Impervious Gowns

ULTRA SPECIALTY GOWN, NON-STERILE, X-LARGE

Features:

- PASSES ASTM1671
- PROPRIETARY 4TH GENERATION SMS FABRIC
- FULL-LENGTH IMPERVIOUS FRONT PANEL & FOREARMS
- PATENTED A-LINE DESIGN FOR SEATED PROCEDURES
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, RED
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- BOOK FOLD

Natural LATEX-FREE NON STERILE

Detail Chart

Stock #	Description	Packaging
76521	ULTRA SPECIALTY GOWN, NON-STERILE, X-LARGE	Case more

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ULTRA Specialty Impervious Gowns

ULTRA SPECIALTY GOWN, STERILE, XX-LARGE

Features:

- PASSES ASTM1671
- PROPRIETARY 4TH GENERATION SMS FABRIC
- FULL-LENGTH IMPERVIOUS FRONT PANEL & FOREARMS
- PATENTED A-LINE DESIGN FOR SEATED PROCEDURES
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - 3 SNAP CLOSURE
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
95531	ULTRA SPECIALTY GOWN, STERILE, XX-LARGE	Case more

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Evolution* 4

- **Standard Surgical Gowns Drop Fold**
- **Standard Surgical Gown Book Fold**
- **Fabric-Reinforced Surgical Gowns**
- **Set-In-Sleeve Surgical Gowns**
- **Tie-Back Fabric-Reinforced**
- **ULTRA* Secure-Fit* Technology**

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Standard Surgical Gowns Drop Fold

Back to Evolution* 4

Stock #	Description
90012	NON-REINFORCED SURGICAL GOWN, STERILE, LARGE
79970	NON-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE
79577	NON-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE, HANDI-BIN
90042	NON-REINFORCED SURGICAL GOWN, STERILE, X-LARGE

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Standard Surgical Gowns Drop Fold

NON-REINFORCED SURGICAL GOWN, STERILE, LARGE

Features:

- EVOLUTION* 4 FABRIC
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - 2 SNAP CLOSURE
- DROP FOLD

Detail Chart

Stock #	Description	Packaging
90012	NON-REINFORCED SURGICAL GOWN, STERILE, LARGE	Case more

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Standard Surgical Gowns Drop Fold

NON-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE

Features:

- EVOLUTION* 4 FABRIC
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- DROP FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
79970	NON-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE	Case more

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Standard Surgical Gowns Drop Fold

NON-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE, HANDI-BIN

Features:

- EVOLUTION* 4 FABRIC
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- DROP FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
79577	NON-REINFORCED SURGICAL GOWN, NON-STERILE, LARGE, HANDI-BIN	Case more

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Standard Surgical Gowns Drop Fold

NON-REINFORCED SURGICAL GOWN, STERILE, X-LARGE

Features:

- EVOLUTION* 4 FABRIC
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- DROP FOLD

LATEX-FREE STERILE CE

Detail Chart

Stock #	Description	Packaging
90042	NON-REINFORCED SURGICAL GOWN, STERILE, X-LARGE	Case more

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Standard Surgical Gowns Drop Fold

- **Standard Surgical Gowns Drop Fold**
- **Standard Surgical Gown Book Fold**
- **Fabric-Reinforced Surgical Gowns**
- **Set-In-Sleeve Surgical Gowns**
- **Tie-Back Fabric-Reinforced**
- **ULTRA* Secure-Fit* Technology**

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Standard Surgical Gown Book Fold

Back to Evolution* 4

Stock #	Description
95011	NON-REINFORCED SURGICAL GOWN, STERILE
95021	NON-REINFORCED SURGICAL GOWN, STERILE, X-LARGE
78221	NON-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE

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Standard Surgical Gown Book Fold

NON-REINFORCED SURGICAL GOWN, STERILE

Features:

- EVOLUTION* 4 FABRIC
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - 2 SNAP CLOSURE
- BOOK FOLD

Natural LATEX-FREE STERILE CE

Detail Chart

Stock #	Description	Packaging
95011	NON-REINFORCED SURGICAL GOWN, STERILE	Case more

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Standard Surgical Gown Book Fold

NON-REINFORCED SURGICAL GOWN, STERILE, X-LARGE

Features:

- EVOLUTION* 4 FABRIC
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - 2 SNAP CLOSURE
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
95021	NON-REINFORCED SURGICAL GOWN, STERILE, X-LARGE	Case more

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Questions? Contact Fips@gate.dcc.com

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Standard Surgical Gown Book Fold

NON-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE

Features:

- EVOLUTION* 4 FABRIC
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- BOOK FOLD

Natural LATEX-FREE NON STERILE CE X

Detail Chart

Stock #	Description	Packaging
78221	NON-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE	Case more

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Standard Surgical Gowns Drop Fold

- **Standard Surgical Gowns Drop Fold**
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Fabric-Reinforced Surgical Gowns

Back to Evolution* 4

Stock #	Description
90112	FABRIC-REINFORCED SURGICAL GOWN, STERILE, LARGE
90142	FABRIC-REINFORCED SURGICAL GOWN, STERILE, X-LARGE
78921	FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE
78927	FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN

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Fabric-Reinforced Surgical Gowns

FABRIC-REINFORCED SURGICAL GOWN, STERILE, LARGE

Features:

- EVOLUTION* 4 FABRIC
- FABRIC REINFORCED CHEST AND SLEEVES
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - 2 SNAP CLOSURE
- DROP FOLD

Natural LATEX-FREE STERILE CE

Detail Chart

Stock #	Description	Packaging
90112	FABRIC-REINFORCED SURGICAL GOWN, STERILE, LARGE	Case more

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Fabric-Reinforced Surgical Gowns

FABRIC-REINFORCED SURGICAL GOWN, STERILE, X-LARGE

Features:

- EVOLUTION* 4 FABRIC
- FABRIC REINFORCED CHEST AND SLEEVES
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING, GREEN
- ADJUSTABLE NECKLINE - 2 SNAP CLOSURE
- DROP FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
90142	FABRIC-REINFORCED SURGICAL GOWN, STERILE, X-LARGE	Case more

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Fabric-Reinforced Surgical Gowns

FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE

Features:

- EVOLUTION* 4 FABRIC
- FABRIC REINFORCED CHEST AND SLEEVES
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING, GREEN
- ADJUSTABLE NECKLINE - 2 SNAP CLOSURE
- DROP FOLD

NON STERILE

CE

Detail Chart

Stock #	Description	Packaging
78921	FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE	Case more

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Fabric-Reinforced Surgical Gowns

FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN

Features:

- EVOLUTION* 4 FABRIC
- FABRIC REINFORCED CHEST AND SLEEVES
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING, GREEN
- ADJUSTABLE NECKLINE - 2 SNAP CLOSURE
- DROP FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
78927	FABRIC-REINFORCED SURGICAL GOWN, NON-STERILE, X-LARGE, HANDI-BIN	Case more

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Standard Surgical Gowns Drop Fold

- **Standard Surgical Gowns Drop Fold**
- **Standard Surgical Gown Book Fold**
- **Fabric-Reinforced Surgical Gowns**
- **Set-In-Sleeve Surgical Gowns**
- **Tie-Back Fabric-Reinforced**
- **ULTRA* Secure-Fit* Technology**

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Set-In-Sleeve Surgical Gowns

Back to Evolution* 4

Stock #	Description
90018	NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, STERILE, LARGE
72878	NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, NON-STERILE, LARGE, HANDI-BIN
79419	NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, LARGE, WITH TOWEL IN OVERWAP, HANDI-BIN
90048	NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, STERILE, X-LARGE
79434	NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, X-LARGE, WITH TOWEL IN OVERWAP, HANDI-BIN

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Set-In-Sleeve Surgical Gowns

NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, STERILE, LARGE

Features:

- EVOLUTION* 4 FABRIC
- SET-IN-SLEEVES
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- LOW LINTING FABRIC
- BOOK FOLD

Natural LATEX-FREE STERILE CE

Detail Chart

Stock #	Description	Packaging
90018	NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, STERILE, LARGE	Case more

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Set-In-Sleeve Surgical Gowns

NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, NON-STERILE, LARGE, HANDI-BIN

Features:

- EVOLUTION* 4 FABRIC
- SET-IN-SLEEVES
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- LOW LINTING FABRIC
- BOOK FOLD

NATURAL LATEX FREE NON STERILE CE

Detail Chart

Stock #	Description	Packaging
72878	NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, NON-STERILE, LARGE, HANDI-BIN	Case more

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Set-In-Sleeve Surgical Gowns

NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, LARGE, WITH TOWEL IN OVERWAP, HANDI-BIN

Features:

- EVOLUTION* 4 FABRIC
- SET-IN-SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- ADJUSTABLE NECKLINE - 2 SNAP CLOSURE
- LOW LINTING FABRIC
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
79419	NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, LARGE, WITH TOWEL IN OVERWAP, HANDI-BIN	Case more

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Set-In-Sleeve Surgical Gowns

NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, STERILE, X-LARGE

Features:

- EVOLUTION* 4 FABRIC
- SET-IN-SLEEVES
- COLOR CODED NECK BINDING
- ADJUSTABLE NECKLINE - HOOK AND LOOP
- LOW LINTING FABRIC
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
90048	NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, STERILE, X-LARGE	Case more

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Set-In-Sleeve Surgical Gowns

NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, X-LARGE, WITH TOWEL IN OVERWAP, HANDI-BIN

Features:

- EVOLUTION* 4 FABRIC
- SET-IN-SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- ADJUSTABLE NECKLINE - 2 SNAP CLOSURE
- LOW LINTING FABRIC
- BOOK FOLD

NON-STERILE

Detail Chart

Stock #	Description	Packaging
79434	NON-REINFORCED SURGICAL GOWN WITH SET-IN-SLEEVES, X-LARGE, WITH TOWEL IN OVERWAP, HANDI-BIN	Case more

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Standard Surgical Gowns Drop Fold

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- **Tie-Back Fabric-Reinforced**
- **ULTRA* Secure-Fit* Technology**

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Tie-Back Fabric-Reinforced

Back to Evolution* 4

Stock #	Description
90212	FABRIC-REINFORCED SURGICAL GOWN, TIE-BACK, STERILE, LARGE
91512	FABRIC-REINFORCED SURGICAL GOWN, TIE-BACK, NON-STERILE, LARGE

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Tie-Back Fabric-Reinforced

FABRIC-REINFORCED SURGICAL GOWN, TIE-BACK, STERILE, LARGE

Features:

- EVOLUTION* 4 FABRIC
- FABRIC REINFORCED CHEST AND SLEEVES
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING
- TIE BACK
- LOW LINTING FABRIC

STERILE

Detail Chart

Stock #	Description	Packaging
90212	FABRIC-REINFORCED SURGICAL GOWN, TIE-BACK, STERILE, LARGE	Case more

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Tie-Back Fabric-Reinforced

FABRIC-REINFORCED SURGICAL GOWN, TIE-BACK, NON-STERILE, LARGE

Features:

- EVOLUTION* 4 FABRIC
- FABRIC REINFORCED CHEST AND SLEEVES
- RAGLAN SLEEVES
- LOW LINTING FABRIC
- COLOR CODED NECK BINDING, GREEN
- TIE BACK
- LOW LINTING FABRIC

NON STERILE

Detail Chart

Stock #	Description	Packaging
91512	FABRIC-REINFORCED SURGICAL GOWN, TIE-BACK, NON-STERILE, LARGE	Case more

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http://nam.kcmkt.com/scripts/cgiip.exe/WA2.exe?ROUTE=DEFAULT&RHAT=SHOW&RMAT=B2C&RCOL=614+142+SIMPLE&RSEL=91512&RTEM=1&RSIZE=1&RSTA=1&RTYP=1&RLIN=0&RLAN=ENU&RCUR=USD&RUNI=EACH&RVER=7.0.0.0

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Standard Surgical Gowns Drop Fold

- **Standard Surgical Gowns Drop Fold**
- **Standard Surgical Gown Book Fold**
- **Fabric-Reinforced Surgical Gowns**
- **Set-In-Sleeve Surgical Gowns**
- **Tie-Back Fabric-Reinforced**
- **ULTRA* Secure-Fit* Technology**

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ULTRA* Secure-Fit* Technology

Back to Evolution* 4

Stock #	Description
90601	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, SMALL
90621	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, X-LARGE
70821	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, X-LARGE
90631	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, XX-LARGE
70631	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, XX-LARGE

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ULTRA* Secure-Fit* Technology

ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, SMALL

Features:

- SECURE-FIT* ANTI-SLIP TECHNOLOGY
- GENEROUS CUT & ADDED LENGTH
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
90601	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, SMALL	Case more

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ULTRA* Secure-Fit* Technology

ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, X-LARGE

Features:

- SECURE-FIT* ANTI-SLIP TECHNOLOGY
- GENEROUS CUT & ADDED LENGTH
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
90621	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, X-LARGE	Case more

Back

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ULTRA* Secure-Fit* Technology

ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, X-LARGE

Features:

- SECURE-FIT* ANTI-SLIP TECHNOLOGY
- GENEROUS CUT & ADDED LENGTH
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
70821	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, X-LARGE	Case more

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ULTRA* Secure-Fit* Technology

ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, XX-LARGE

Features:

- SECURE-FIT* ANTI-SLIP TECHNOLOGY
- GENEROUS CUT & ADDED LENGTH
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING
- BOOK FOLD

STERILE

Detail Chart

Stock #	Description	Packaging
90631	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, STERILE, XX-LARGE	Case more

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ULTRA* Secure-Fit* Technology

ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, XX-LARGE

Features:

- SECURE-FIT* ANTI-SLIP TECHNOLOGY
- GENEROUS CUT & ADDED LENGTH
- RAGLAN SLEEVES
- COLOR CODED NECK BINDING, YELLOW
- BOOK FOLD

NON STERILE

Detail Chart

Stock #	Description	Packaging
70631	ULTRA NON-REINFORCED* SURGICAL GOWN WITH SECURE-FIT* TECHNOLOGY, NON-STERILE, XX-LARGE	Case more

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APPENDIX V

Labeling provided for the surgical gowns cleared in K781662 and K842115 that demonstrates the use of term “impervious” and “low linting”.

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Labeling in K781662

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6/27/74

APPROVAL	
NAME	DATE

Job No: 1506

Project: New KIMGUARD Gown Collateral

COPY

COVER

Fssssst! Finally, A Disposable Gown Your Surgeons Will Wear. Fssssssssssssssssst!

It's Not Paper.

INSIDE

New KIMGUARD(TM) Surgical Gown

Special 'breathable' non-woven fabric eliminates many of the undesirable characteristics associated with disposable gowns.

CAPTIONS

Soft, like cloth - eliminates stiffness and rustling.

Breathable - more comfort, less heat build-up during long procedures.

Lightweight - only 1/3 the weight of muslin gowns.

Seamless - special ultra-sonic construction eliminates needle holes, and needle hole fluid 'strike-through'.

Improved Bacterial Barrier - sterile covering for your surgical team, plus outstanding filter medium to contain shed skin particles and retard bacterial migration.

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1508/2

Fluid Repellent - to reduce risk of cross-contamination resulting from fluid 'strike-through'.

Extremely Low Lint - depending on particle size, some muslin gowns have up to 100 times more lint.

Tough Cuff - material is strong to help eliminate gown cuff tearing away from gown or accidental tear holes in sleeve when surgeon adjusts cuff and gloves.

Eliminates Time-Consuming, Costly Processing - Disposabliity eliminates laundering, inspecting, delinting, patching, folding, wrapping and sterilizing.

INSERT FLAP

Psssssssssssssst! It's Not Paper .

(KC)

Kimberly-Clark Corporation

Hospital Products

BACK

Form No _____

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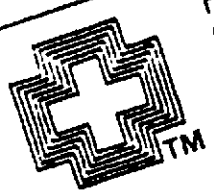
Kimguard™ Surgical Gowns



Health-Care Products
Kimberly-Clark Corporation

Contents sterile unless this package is opened or damag
Remove outside film dust co
prior to use near hazardous
atmosphere

One **Medium** overlap back style surgical gown
Reorder No. 10400

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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STERILE SINGLE-PATIENT PRODUCTS FOR SURGERY

Stock Number	SM I SURGICAL GOWNS	Gowns Per Case	Case Weight	CASE PRICE 750	500	250	100	50	10
	FULL OVERLAP BACK STYLE COMFORTAB® Closure								
67130	Medium, 1 Gown per pkg.	24	18 lbs.	$52.25	$53.40	$54.45	$55.50	$57.05	$61.25
67140	Large, 1 Gown per pkg.	24	19 lbs.	55.30	56.40	57.50	53.50	60.25	64.70
69000	Large, 2 Gowns per pkg.	24	16 lbs.	52.85	53.90	55.00	56.05	57.60	61.35
67132	Medium, 1 Gown per pkg. w/protective panels	24	20 lbs.	57.05	58.20	59.35	60.50	62.20	66.75
67142	Large, 1 Gown per pkg. w/protective panels	24	21 lbs.	59.95	61.15	62.35	63.55	65.35	70.15
	STANDARD OVERLAP BACK STYLE								
69270	Medium, 1 Gown per pkg.	24	18 lbs.	46.80	47.75	48.65	49.60	51.00	54.75
69280	Large, 1 Gown per pkg.	24	18.5 lbs.	51.30	52.35	53.40	54.40	55.95	60.05
69290	Large, 2 Gowns per pkg.	24	18 lbs.	48.90	49.85	50.65	51.60	53.30	57.20

Stock Number	SM II SURGICAL GOWNS	Gowns Per Case	Case Weight	CASE PRICE 750	500	250	100	50	10
	FULL OVERLAP BACK STYLE COMFORTAB® Closu								
69050	Medium, 1 Gown per pkg.	24	18 lbs.	585.75	587.05	568.35	569.65	571.65	578.90
69060	Large, 1 Gown per pkg.	24	18 lbs.	67.20	68.55	69.50	71.25	73.25	67.05
69070	Large, 2 Gowns per pkg.	24	18 lbs.	65.90	67.20	68.55	69.65	71.05	77.10
69061	Large, 1 Gown per pkg. w/protective panels	24	21 lbs.	74.60	76.10	77.60	79.10	81.33	87.30

78.65

Stock Number	COMPONENTS	Items Per Pkg.	Items Per Case	Case Weight	CASE PRICE 750	500	250	100	50	10
67620	Small Drape Sheet 15"x30"	2	50	4 lbs.	$14.65	$14.05	$15.25	$15.55	$16.00	$17.15
67300	Regular Drape Sheet 48"x60"	1	25	9 lbs.	24.35	24.05	25.25	25.00	26.55	28.50
67700	Large Drape Sheet 60"x78"	1	25	13 lbs.	41.35	42.20	43.00	43.05	46.10	48.40
69120	Small Fenestrated Sheet 30"x30"	1	25	9 lbs.	30.65	31.25	31.85	32.50	33.40	35.85
67650	Small Split Sheet 60"x78"	1	25	14 lbs.	63.75	65.05	66.30	67.60	69.55	74.60
67550	Large Split Sheet 78"x120"	1	10	14 lbs.	44.35	45.25	46.15	47.00	48.35	51.00
67530	Winged Laparotomy Sheet 106"x120"	1	10	18.5 lbs.	51.30	52.30	53.35	54.35	55.90	60.00
67540	Ear Sheet 48"x100"	1	10	10 lbs.	28.35	29.95	30.55	31.10	32.00	34.35
67680	Laparotomy Sheet 78"x120"	1	10	14 lbs.	44.35	45.25	46.15	47.00	48.35	51.90
67560	Transverse Lap Sheet 78"x120"	1	10	14 lbs.	45.20	46.10	47.00	47.95	49.20	52.00
67600	Pediatric Lap Sheet 60"x108"	1	10	9 lbs.	32.90	33.55	34.20	34.90	35.85	38.50
67590	Under Buttock Drape 40"x44"	1	25	13 lbs.	26.65	27.20	27.75	28.25	29.05	31.20
69100	Orthopedic Sheet 60"x78"	1	10	14 lbs.	25.40	25.90	26.45	26.95	27.70	29.75
69110	Thyroid Sheet 78"x120"	1	10	19 lbs.	44.35	45.25	46.15	47.00	48.35	51.00
67080	Legging 34"x40"	1	25	10 lbs.	28.00	28.55	29.10	29.65	30.50	32.75
67010	Microbent Towel 15"x30"	5	125	9 lbs.	19.85	20.25	20.60	21.00	21.60	23.20
67020	Table Cover 45"x78"	1	25	10 lbs.	27.80	28.35	28.90	29.45	30.30	32.50
67670	Mayo Stand Cover 25"x54"	1	25	11 lbs.	29.05	29.65	30.20	30.80	31.65	34.00
69150	Chest Sheet 78"x120"	1	10	11 lbs.	52.40	53.45	54.50	55.55	57.10	61.30
69160	Knee Sheet 78"x120"	1	10	[illegible] lbs.	51.90	52.95	54.00	55.05	56.60	60.75
69170	U Sheet 78"x120"	1	10	12 lbs.	54.20	55.25	56.35	57.45	59.05	63.40
69180	Orthopedic Stocking	1	10	6.4 lbs.	29.05	27.20	27.75	28.25	29.05	31.20

* AVAILABLE 1/2/[illegible]

[illegible] 11/25. [illegible]

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Labeling in K842115

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SURGICAL PRODUCTS—STERILE

Stock Number	SPUNGUARD® SURGICAL PACKS	Packs Per Case	Cube
88731	**CARDIOVASCULAR PACK** 1 Back Table Cover, Reinforced [illegible] x 44" 1 Surgical Gown, Large (90112) with Hand Towel in Overwrap 2 Hand Towels 30" x 15" 2 Surgical Gowns, Large (90112) 1 Mayo Stand Cover, Reinforced [illegible] x 55" 1 Operating Table Cover [illegible] • ISO SEAL® Positioning Tape • CONTROL® Fabric Reinforcement 3 Absorbent Towels [illegible] 2 Sterile Foot Covers 1 Perineum Cover • ISO SEAL® Positioning Tape 1 Urinalysis Cover 30" [illegible] 6 Utility Drapes 30" x 15" • ISO SEAL® Positioning Tape 1 [illegible] — 1 Cardiovascular Sheet [illegible] x 110" with [illegible] Towels 20" and 4" x [illegible] Tape • ISO SEAL® Positioning Tape • CONTROL® Fabric Reinforcement • Plastic Pouch on Pump Tubing Towels 1 Large Drape 60" x 77"	2	1.72
88811	**OB PACK I** 1 Back Table Cover, Reinforced 78" x 44" 1 Set-Up Cover 77" x 44" 2 Absorbent Towels 30" x 15" 1 Under Buttocks Drape 38½" x 44" • Poly Reinforcement 2 Leggings 30" x 37" 1 Abdominal Drape 38½" x 60" • ISO SEAL® Positioning Tape • CONTROL® Fabric Reinforcement	8	1.72
88821	**OB PACK II** 1 Back Table Cover, Reinforced 78" x 44" 1 Set-Up Cover 77" x 44" 2 Absorbent Towels 30" x 15" 1 Under Buttocks Drape 38½" x 44" • Poly Reinforcement 2 Leggings 30" x 37" 1 Abdominal Drape 38½" x 60" • ISO SEAL® Positioning Tape • CONTROL® Fabric Reinforcement 1 Vaginal Packing Sponge 2 Peri Pads 1 Hollister® Cord Clamp 1 Placenta Basin	5	1.72
88831	**OB PACK III** 1 Back Table Cover, Reinforced 78" x 44" 1 Set-Up Cover 77" x 44" 1 Hand Towel 30" x 15" 1 Surgical Gown, Large/Tie-Back (90212) 2 Absorbent Towels 30" x 15" 1 Baby Blanket 36" x 30" 1 Under Buttocks Drape 38½" x 44" • Poly Reinforcement 2 Leggings 30" x 37" 1 Abdominal Drape [illegible] • ISO SEAL® Positioning Tape • CONTROL® Fabric Reinforcement 1 Vaginal Packing Sponge 2 Peri Pads 1 Hollister® Cord Clamp 1 Placenta Basin 1 [illegible]	5	2.01

Stock Number	SPUNGUARD® SURGICAL GOWNS		Items Per Package	Items Per Case	Cube
90102	SMALL	Sterile Back with Hand Towel(s)	1	32	2.01
90112	LARGE		1	32	2.01
90122	LARGE		2	32	2.01
90132	LARGE		3	32	2.01
90142	X LARGE		1	30	2.01
90212	LARGE	Tie Back with Hand Towel	1	31	2.01
90312	LARGE	Sterile Back with Impervious Reinforcements and Hand Towel	1	32	2.01
90342	X LARGE		1	30	2.01
90412	LARGE	Sterile Back Specially Impervious with Hand Towel	1	[illegible]	[illegible]
90442	X LARGE		1	[illegible]	[illegible]

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ATTACHMENT 2 (CONTINUED)

SURGIDAY SYSTEM

90720

Surgical Gown

1 Surgical Gown
Sterile Back/Small
☐ 1 Absorbent Towel
☐ 1 CSR Wrap, 25" x 25"

Contents Sterile
Unless The Package Is Opened Or Damaged.
Single-Use Product. Do Not Reuse

Kimberly-Clark Corporation
Health Care Products Group
Roswell, GA 30076

Assembled in Mexico of U.S.-made materials.

CONTROL NO.

SURGIDAY SYSTEM IS A TRADEMARK OF KIMBERLY-CLARK CORPORATION.

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APPENDIX VI

Substantial equivalence tables comparing the current legally marked predicate devices under K781682 and K842115 to the new devices under submission. A separate substantial equivalence table is provided for the Ultra Surgical Gowns with AAMI Level 3 and Ultra Film-Reinforced Gowns with AAMI Level 4 claims.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix VI.A

Table for Appendix VI.A - Substantial Equivalence Comparison of the Ultra Surgical Gowns with AAMI Liquid Barrier Level 3 Claims to Currently Marketed Predicate Ultra Surgical Gowns.

Attribute	Predicates K781682 Kimberly-Clark* KIMGUARD*	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns, currently marketed as the Ultra Surgical Gowns	Subject of this 510(k): ULTRA Surgical Gown with AAMI Level 3 Claims
Classification Code	FYA	KKX (Note KKX, which is a surgical drape code, was likely assigned to K842115 by FDA as the submission consisted of a bundle of drapes, gowns, and surgical packs.)	FYA
FDA Device Class	Class 2	Same	Same
Common Device Name	Surgical gown, sterile	Same	Same
Indications for Use	Surgical Gowns are sterile, disposable products for use by operating room personnel during surgical procedures.	Same	*Equivalent use, but the Indications for Use have been updated to reflect current industry focus on gown barrier properties and in accordance with 21 CFR 878.4040 as follows:* The Kimberly-Clark* ULTRA Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gowns meet Level 3 of the AAMI Liquid Barrier classifications.

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Attribute	Predicates K781682 Kimberly-Clark* KIMGUARD*	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns, currently marketed as the Ultra Surgical Gowns	Subject of this 510(k): ULTRA Surgical Gown with AAMI Level 3 Claims
How Supplied	Single use, sterile, disposable	Same	Same
Construction			
Gown Color	Blue	Same	Same
Gown Sizes	Medium, Large	Small, Large, X-Large, and XX-Large	Small, Large, X-Large, and XX-Large
Construction Overview	(b)(4) [redacted]		
Neck Binding Pigments			
Fabric			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attribute	Predicates K781682 Kimberly-Clark* KIMGUARD*	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns, currently marketed as the Ultra Surgical Gowns	Subject of this 510(k): ULTRA Surgical Gown with AAMI Level 3 Claims
Cuff	(b)(4) [redacted]		
Neck Closure, Loop			
Neck Closure, Hoop			
Adhesive			
Back Tie Tape			
Front Tie Tape			
Thread			
Ink			
Blue Pigment			
White Pigment			
Anti-Stat treatment			
Repellency Treatment			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attribute	Predicates K781682 Kimberly-Clark* KIMGUARD*	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns, currently marketed as the Ultra Surgical Gowns	Subject of this 510(k): ULTRA Surgical Gown with AAMI Level 3 Claims
Latex Free	Yes	Same	Same
Basis Weight per ASTM1 D3776 -07 Standard Test Methods for Mass Per Unit Area (Weight) of Fabric	n/a	(b)(4) [redacted] (ounces per square yard) Body (b)(4) [redacted] Sleeve	Same
Mechanical Design Attributes			
Resistance to blood and liquid penetration	Fabric possesses bacterial barrier properties and repellency to aqueous fluids.	Same	Meets ANSI/AAMI PB70:2003 *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* for AAMI Level 3. The entire front of the gown (critical zones A, B, and C) meets the following at AQL 4.0: • Spray Impact ≤ 1.0 g • Hydrostatic Head ≥ 50 cm

[1] American Society for Testing and Materials (international)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attribute	Predicates K781682 Kimberly-Clark* KIMGUARD*	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns, currently marketed as the Ultra Surgical Gowns	Subject of this 510(k): ULTRA Surgical Gown with AAMI Level 3 Claims
Linting (per INDA Standard Test Methods IST 160.1-01 Resistance to Linting of Nonwoven Fabric (Dry))	n/a	Claim of "relatively lint-free" . ≤ (b)(b) particles, 10.0 micron in diameter	No claim of "relatively lint free" is being made for new Ultra Surgical Gowns under submission. However, the Ultra Surgical Gowns under submission do provide acceptable linting per INDA Standard Test Method IST 160.1-01 Resistance to Linting of Nonwoven Fabric (Dry), ≤ 10 particles, 10.0 micron in diameter.
Grab Tensile Strength (CD/MD[2]) per ASTM D 5034-95 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test))	n/a	(b).0 lbf	Same
Static Dissipation per INDA[3] Standard Test Methods IST 40.2-01 Electrostatic Decay of Nonwoven Fabrics	n/a	≤ (b) seconds	Same
Flame Resistance of NonWoven Fabrics (30 second burn challenge) per NFPA[4] 702-1980, specifications for fabrics without raised-fiber surfaces	n/a	Class 1 ≥ 20 second flame spread time	Same

[2] CD = Cross direction orientation of the fabric, in relation to machine direction (MD) during manufacture
[3] Association of the Nonwoven Fabrics Industry
[4] National Fire Prevention Association

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attribute	Predicates K781682 Kimberly-Clark* KIMGUARD*	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns, currently marketed as the Ultra Surgical Gowns	Subject of this 510(k): ULTRA Surgical Gown with AAMI Level 3 Claims
Safety Attributes			
Safety Attributes	Met industry standards for biocompatibility: short term muscle implant study, long term muscle implant study, introperitoneal implant study, irritation.	Passes ISO 10993 biocompatibility testing for cytotoxicity, irritation, and sensitization	Same Passes ISO 10993 biocompatibility testing for cytotoxicity, irritation, and sensitization.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Appendix VI.B

Table for Appendix VI.A - Substantial Equivalence Comparison of the Ultra Film-Reinforced Surgical Gowns with AAMI Liquid Barrier Level 4 Claims to Currently Marketed Predicate Ultra Impervious Surgical Gowns.

Attribute	**Predicates K781682 Kimberly-Clark* KIMGUARD***	**Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns with Impervious Reinforcements, currently marketed as the Ultra Impervious Surgical Gowns**	**Subject of this 510(k): ULTRA Film-Reinforced Surgical Gowns with AAMI Level 4 Claims**
Classification Code	FYA	KKX (Note KKX, which is a surgical drape code, was likely assigned to K842115 by FDA as the submission consisted of a bundle of drapes, gowns, and surgical packs.)	FYA
FDA Device Class	Class 2	Same	Same
Common Device Name	Surgical gown, sterile	Same	Same
Indications for Use	Surgical Gowns are sterile, disposable products for use by operating room personnel during surgical procedures.	Same	*Equivalent use, but the Indications for Use have been updated to reflect current industry focus on gown barrier properties and in accordance with 21 CFR 878.4040 as follows:* The Kimberly-Clark* ULTRA Film-Reinforced Surgical Gowns are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Film-Reinforced Surgical Gowns meet Level 4 of the AAMI Liquid Barrier classifications.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attribute	Predicates K781682 Kimberly-Clark* KIMGUARD*	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns with Impervious Reinforcements, currently marketed as the Ultra Impervious Surgical Gowns	Subject of this 510(k): ULTRA Film-Reinforced Surgical Gowns with AAMI Level 4 Claims
How Supplied	Single use, sterile, disposable	Same	Same
Construction			
Gown Color	Blue	Same	Same
Gown Sizes	Medium, Large	Small, Large, X-Large, and XX-Large	Small, Large, X-Large, and XX-Large
Construction Overview	(b)(4) [redacted]		
Outer Facing			
Outer Facing Adhesive			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attribute	Predicates K781682 Kimberly-Clark* KIMGUARD*	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns with Impervious Reinforcements, currently marketed as the Ultra Impervious Surgical Gowns	Subject of this 510(k): ULTRA Film-Reinforced Surgical Gowns with AAMI Level 4 Claims
Neck Binding Pigments	[redacted]	(b)(4)	[redacted]
Fabric	[redacted]	[redacted]	[redacted]
Cuff	[redacted]	[redacted]	[redacted]
Neck Closure, Loop	[redacted]	[redacted]	[redacted]
Neck Closure, Hoop	[redacted]	[redacted]	[redacted]
Adhesive	[redacted]	[redacted]	[redacted]
Back Tie Tape	[redacted]	[redacted]	[redacted]
Front Tie Tape	[redacted]	[redacted]	[redacted]
Thread	[redacted]	[redacted]	[redacted]
Ink	[redacted]	[redacted]	[redacted]
Blue Pigment	[redacted]	[redacted]	[redacted]
White Pigment	[redacted]	[redacted]	[redacted]
Anti-Stat treatment	[redacted]	[redacted]	[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Attribute	Predicates K781682 Kimberly-Clark* KIMGUARD*	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns with Impervious Reinforcements, currently marketed as the Ultra Impervious Surgical Gowns	Subject of this 510(k): ULTRA Film-Reinforced Surgical Gowns with AAMI Level 4 Claims
Repellency Treatment	[redacted]	(b)(4) [redacted]	Same
Latex Free	Yes	Same	Same
Basis Weight per ASTM1 D3776 -07 Standard Test Methods for Mass Per Unit Area (Weight) of Fabric	n/a	(b)(4) [redacted] (ounces per square yard) Body and Sleeve	Same
Mechanical Design Attributes			
Resistance to blood and liquid penetration	Fabric possesses bacterial barrier properties and repellency to aqueous fluids.	Same	Meets ANSI/AAMI PB70:2003 *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* for AAMI Level 4. The entire front of the gown (critical zones A, B, and C) meets the following at AQL 4.0: • Passes ASTM F 1671

[1] American Society for Testing and Materials (international)

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attribute	Predicates K781682 Kimberly-Clark* KIMGUARD*	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns with Impervious Reinforcements, currently marketed as the Ultra Impervious Surgical Gowns	Subject of this 510(k): ULTRA Film-Reinforced Surgical Gowns with AAMI Level 4 Claims
Linting (per INDA Standard Test Methods IST 160.1-01 Resistance to Linting of Nonwoven Fabric (Dry))	n/a	Claim of "relatively lint-free" . ≤ (b)(4) [redacted] micron in diameter	No claim of "relatively lint free" is being made for new ULTRA Film-Reinforced Surgical Gowns under submission. However, the surgical gowns under submission do provide acceptable linting per INDA Standard Test Method IST 160.1-01 Resistance to Linting of Nonwoven Fabric (Dry), ≤ (b)(4) [redacted] in diameter.
Grab Tensile Strength (CD/MD[2]) per ASTM D 5034-95 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test))	n/a	(b) [redacted] lbf	Same
Static Dissipation per INDA3 Standard Test Methods IST 40.2-01 Electrostatic Decay of Nonwoven Fabrics	n/a	≤ ([redacted] seconds	Same

[2] CD = Cross direction orientation of the fabric, in relation to machine direction (MD) during manufacture
[3] Association of the Nonwoven Fabrics Industry

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

Attribute	Predicates K781682 Kimberly-Clark* KIMGUARD*	Predicate K842115 Kimberly-Clark* SPUNGUARD* Surgical Gowns with Impervious Reinforcements, currently marketed as the Ultra Impervious Surgical Gowns	Subject of this 510(k): ULTRA Film-Reinforced Surgical Gowns with AAMI Level 4 Claims
Flame Resistance of NonWoven Fabrics (30 second burn challenge) per NFPA[4] 702-1980, specifications for fabrics without raised-fiber surfaces	n/a	Class 1 ≥ 20 second flame spread time	Same
Safety Attributes			
Safety Attributes	Met industry standards for biocompatibility: short term muscle implant study, long term muscle implant study, introperitoneal implant study, irritation.	Passes ISO 10993 biocompatibility testing for cytotoxicity, irritation, and sensitization.	Same Passes ISO 10993 biocompatibility testing for cytotoxicity, irritation, and sensitization.

[4] National Fire Prevention Association

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

APPENDIX VII

Labeling and promotional material for the new ULTRA Surgical Gowns and ULTRA Film-Reinforced Surgical Gowns with AAMI Level 3 and 4 liquid barrier claims under submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The Contents Statement that is Placed on Every Gown Package

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

4/5/07
10-60-204-0-03
Medium Top Web - Back (rotated 180°)
2 x 2 Cutting Die
Prints PMS 420 Gray

(EN) **CONTENTS STERILE.** Unless this package is opened or damaged. **CAUTION: Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia. Natural Rubber Latex Free.**
(FR) **STÉRILE.** Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation. **ATTENTION : Éviter tout contact avec des sources potentielles de feu. Ne pas utiliser en présence d'un produit anesthésique inflammable. Ne contient pas de latex de caoutchouc naturel.**
(DE) **STERIL,** solange die Packung nicht geöffnet oder beschädigt ist. **VORSICHT: Nicht mit potenziellen Zündquellen in Berührung kommen lassen. Nicht in Anwesenheit von entzündlichen Narkosemitteln verwenden. Enthält kein Naturkautschuk-Latex.**
(BG) **СЪДЪРЖАНИЕТО Е СТЕРИЛНО** ако опаковката не е отворена или повредена. **ВНИМАНИЕ: Да се избягва контакт с потенциални източници на запалване. Да не се използват при наличие на запалима упойка. Без съдържание на латекс от естествен каучук.**
(ES) **CONTENIDO ESTÉRIL,** a no ser que este paquete esté abierto o dañado. **PRECAUCIÓN: evite el contacto con fuentes potenciales de combustibilidad. No utilizar en presencia de anestesias inflamables. No contiene látex de goma natural.**
(CS) **OBSAH JE STERILNÍ,** pokud se balení neotevře nebo nepoškodí. **POZOR: vyvarujte se kontaktu s potenciálními zdroji ohně. Nepoužívejte v blízkosti hořlavých anestetických látek. Neobsahuje přírodní kaučuk.**
(DA) **INDHOLDET ER STERILT** med mindre pakken er åbnet eller beskadiget. **ADVARSEL: Undgå kontakt med mulige antændningskilder. Må ikke bruges i nærheden af brandbare bedøvelsesmidler. Indeholder ikke naturgummilatex.**
(ET) **STERIILNE** välja arvatud juhul, kui pakend on avatud või kahjustatud. **ETTEVAATUST: Vältida kokkupuudet süütekoldega. Mitte kasutada süttivate anesteetikumide läheduses. Ei sisalda naturaalset kummilateksit.**
(EL) **ΑΠΟΣΤΕΙΡΩΜΕΝΟ ΠΕΡΙΕΧΟΜΕΝΟ:** Εφόσον η συσκευασία δεν είναι ανοιγμένη ή κατεστραμμένη. **ΠΡΟΣΟΧΗ: Αποφύγετε την επαφή με πιθανές πηγές ανάφλεξης. Μην τις χρησιμοποιείτε κοντά σε εύφλεκτα αναισθητικά. Δεν περιέχει λατέξ από φυσικό καουτσούκ.**
(IT) **CONTENUTO STERILE.** Verificare che la confezione sia integra prima dell'uso. **AVVERTENZA: Evitare il contatto con potenziali sorgenti di accensione. Non utilizzare in presenza di gas anestetici infiammabili. Non contiene lattice di gomma naturale.**
(LV) **STERILS SASTĀVS.** Iznēmot, ja iepakojums atvērts vai bojāts. **PIESARDZĪBA: Jāizsargājas no kontakta ar iespējamiem aizdedzes avotiem. Nelietot viegli uzliesmojošu anestēzijas vielu klātbūtnē. Bez dabiskās gumijas lateksa.**
(LT) **PAKUOTĖS TURINYS STERILUS,** kol ši pakuotė neatidaryta ar nepažeista. **ATSARGIAI: saugoti nuo potencialių ugnies šaltinių. Nenaudoti greta degių anestetinių medžiagų. Sudėtyje nėra natūralaus kaučiuko latekso.**
(HU) **A TARTALMA STERIL** kivéve, ha a csomag fel van nyitva vagy sérült. **VESZÉLY: Kerüljük a potenciális tűzforrással való érintkezést. Ne használjuk gyúlékony érzéstelenítő szerek jelenlétében. Nem tartalmaz természetes gumi latexet.**
(NL) **INHOUD STERIEL.** Tenzij de verpakking open of beschadigd is. **OPGELET: Contact met mogelijke ontstekingsbronnen vermijden. Niet gebruiken in de aanwezigheid van licht ontvlambare anesthetica. Bevat geen natuurlijke rubberlatex.**
(NO) **STERILT INNHOLD.** Sterile med mindre pakken er åpnet eller skadet. **OBS! Unngå kontakt med potensielle tennkilder. Skal ikke brukes nær ildsfarlige anestesimidler. Inneholder ikke naturgummi.**
(PL) **MATERIAŁ WYJAŁOWIONY.** O ile opakowanie nie zostało otwarte lub uszkodzone. **PRZESTROGA: Należy unikać kontaktu z potencjalnymi źródłami zapłonu. Nie należy używać w obecności łatwopalnych środków anestezjologicznych. Nie zawiera naturalnej gumy lateksowej.**
(PT) **CONTEUDO ESTERILIZADO.** Verificar a integridade do protector individual de esterilidade antes de usar. **ATENÇÃO: Evitar o contacto com possíveis fontes de ignição. Não usar na presença de gás inflamável de anestesia. Não contém látex de borracha natural.**
(RO) Acest pachet are un **CONȚINUT STERIL** dacă nu a fost deschis sau avariat. **AVERTISMENT: A se evita contactul cu surse posibile de aprindere. A nu se folosi în prezența anestezicelor inflamabile. Produsul nu conține latex din cauciuc natural.**
(RU) **СОДЕРЖИМОЕ СТЕРИЛЬНО,** если упаковка не открыта или повреждена. **ОСТОРОЖНО: избегайте контактов с возможными источниками возгорания. Не использовать в присутствии горючего анестетика. Не содержит латекса натуральной резины.**
(SK) **OBSAH JE STERILNÝ,** ak sa balenie neotvorí alebo nepoškodí. **POZOR: Vyhnite sa kontaktu s potenciálnymi zdrojmi ohňa. Nepoužívajte v blízkosti horľavých anestetických látok. Neobsahuje prírodný latex.**
(SL) **VSEBINA STERILNA.** Razen v primeru, da je paket odprt ali poškodovan. **OPOZORILO: Izogibajte se stiku z morebitnimi viri vžiga. Ne uporabljajte v prisotnosti vnetljive anestezije. Brez naravnega lateksa iz kavčuka.**
(FI) **SISÄLTÖ ON STERIILI.** Jos tämä pakkaus on avaamaton ja vahingoittumaton. **VAROITUS: Vältettävä kosketusta mahdollisiin sytytyslähteisiin. Ei saa käyttää helposti syttyvien anesteettien lähellä. Ei sisällä luonnonkumilateksia.**
(SV) **INNEHÅLLET STERILT.** Utom om förpackningen har öppnats eller skadats. **VAR FÖRSIKTIG: Undvik kontakt med potentiella antändningskällor. Använd inte i närheten av brandfarliga anestetika. Innehåller inte naturgummilatex.**
(TR) Paket açılmamış yada zarar görmemişse **MUHTEVİYATI STERİLDİR. UYARI: Muhtemel parlayıcı kaynaklardan uzak tutunuz. Yanıcı anestezi maddesi olan yerde kullanmayınız. Doğal Kauçuk Lateks İçermez.**
(JA) **内容物は滅菌済み** 包装が開封または破損していない限り。**注意：着火源となる可能性のある物との接触を避けてください。可燃性麻酔剤の近くで使用しないこと。天然ゴムラテックスは含まれていません。**
(ZH) **成分无菌，除非包装被打开或损坏。注意：避免接触在燃烧源 现场有可燃麻醉剂时不要使用 无天然胶乳。**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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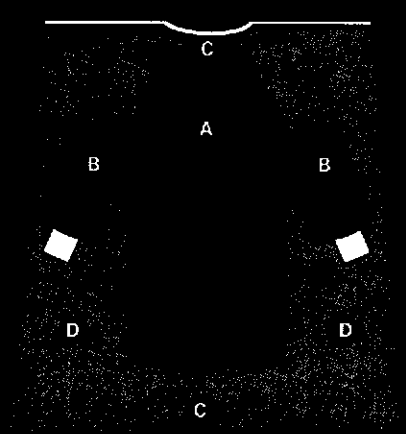
The Ultra Surgical Gown Product Brochure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016



AAMI Liquid Barrier Standard: Now for ULTRA Surgical Gowns

- **AAMI Level 3:**

  ULTRA Surgical Gowns provide Level 3 liquid barrier in zones A, B, and C

- **AAMI Level 4:**

  The ULTRA Film-Reinforced Surgical Gowns provide Level 4 liquid barrier in zones A, B, and C

[1]ANSI/AAMI PB70:2003 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

KIMBERLY-CLARK* ULTRA Gowns Meet AAMI Liquid Barrier Standard[1]

The liquid barrier standard for classification of protective apparel and drapes for use in hospital facilities has been introduced by the Association for the Advancement of Medical Instrumentation (AAMI) to assist healthcare personnel in the selection and use of surgical gowns, drapes, and other protective apparel.

The AAMI Liquid Barrier Standard is used widely and is now recognized by the FDA as a standard for barrier testing, classification, performance claims, and product labeling of surgical gowns.

AAMI: Defining the Critical Zones

AAMI liquid barrier performance levels are classified from Level 1 through Level 4, with Level 4 being the highest liquid barrier level. These levels apply to the product's Critical Zones. For surgical gowns, the critical zones are, at a minimum, the front area of the gown from chest to knees (area A) and the sleeves from the cuff to above the elbow (area B). The standard requires that the entire front of a surgical gown (Areas A, B, and C) provide a liquid barrier of at least Level 1. The back of the gown (area D) may be non-protective.

AAMI Classification of liquid barrier performance of surgical gowns, surgical drapes and drape accessories

Level	Test	Description	Result	AQL requirement
1	AATCC 42:2000	Impact penetration	≤ 4.5 g	4%
2	AATCC 42:2000 AATCC 127:1998	Impact penetration Hydrostatic pressure	≤ 1.0 g ≥ 20 cm	4% 4%
3	AATCC 42:2000 AATCC 127:1998	Impact penetration Hydrostatic pressure	≤ 1.0 g ≥ 50 cm	4% 4%
4	ASTM F1671:2003	Resistance to bacteriophage (surgical gowns and other protective apparel)	Pass	4%
	ASTM F1670:2003	Resistance to synthetic blood (surgical drapes and drape accessories)	Pass	4%

DRAFT

Kimberly-Clark
*Trusted Clinical Solutions**

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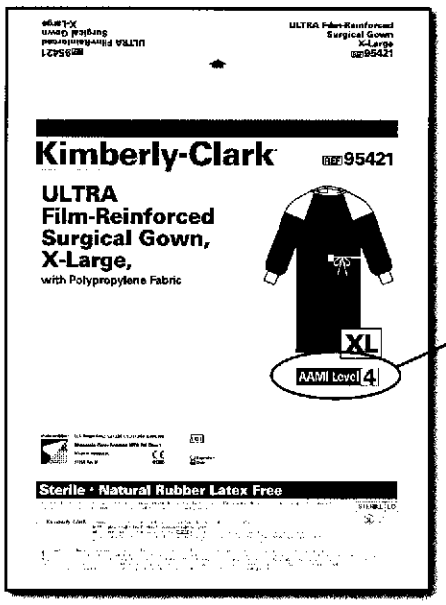
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

FOIA Request # 2015-9647; Released by CDRH on 03-28-2016



"At the shelf" selection is where AAMI liquid barrier classification provides its greatest benefit, through informative product labeling. You will find the AAMI level clearly indicated on each gown package and case label. In addition, the AAMI level is stamped on the inside of each gown.

AAMI Level 4

"Surgical gowns and drapes should be resistant to penetration by blood and other bodily fluids as necessitated by their intended use. Ultimately, blood and other bodily fluids are vehicles for bacterial and viral transmission."

— AORN 2004 Standards, Recommended Practices and Guidelines

DRAFT

Commitment to Excellence
If, for any reason, our products do not meet your expectations, please let us know your comments or suggestions for improvement. Your input will result in a concerted effort on our part to meet your requirements. Our goal is to provide quality products that completely meet your needs time after time.

For more information, please call your sales representative, or visit our web site at www.kchealthcare.com.

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H0707-07-01

Kimberly-Clark
*Trusted Clinical Solutions**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2-Label Set (Box and Package)
Representative for the ULTRA Surgical Gown

(for Reference No. 95101, Small)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

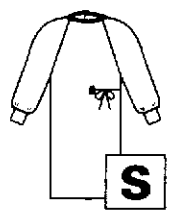
6"

6.75"

Kimberly-Clark*

ULTRA Surgical Gown, Small

with Polypropylene Fabric



AAMI Level 3

34

(34 x 1)

Single Use Only

REF **95101 35**

STERILE EO

LOT

Expiration Date

Made in Honduras

00000000000

CE 0086

1"

DRAFT

5/27/08 • THERMAL CASE LABEL • 6" x 6.75"

If UL items are prepacked on previously approved label stock

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

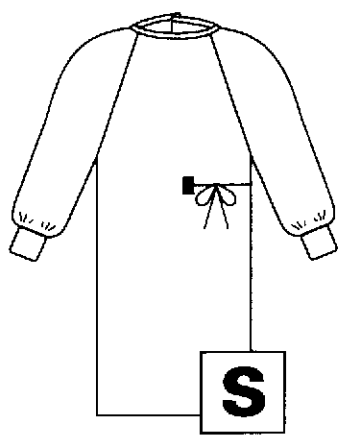
ULTRA Surgical Gown
Small
REF 95101

ULTRA Surgical Gown
Small
REF 95101

Kimberly-Clark

REF 95101

ULTRA Surgical Gown, Small
with Polypropylene Fabric



AAMI Level 3

EVOLUTION
U.S. Patent Nos. 5,277,883; 5,277,883; 5,464,688
Disposable, Flame Resistant NFPA 702 Class 1
Made in Honduras
CE 0086
4946-2674-03

LOT

Expiration Date

Sterile : Natural Rubber Latex Free

DRAFT

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

2-Label Set (Box and Package)
Representative for the ULTRA Surgical Gown, Two-Pack

(for Reference No. 95055, Large, Two-Pack)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

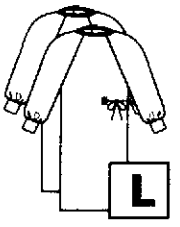
6"

6.75"

Kimberly-Clark*

ULTRA Surgical Gown, Large

with Polypropylene Fabric Two-Pack



AAMI Level 3

32
(16 x 2)

Single Use Only

REF 95055 25

STERILE EO

LOT

Expiration Date

Made in Honduras

00000000000

CE 0086

1"

DRAFT

5/27/08 • THERMAL CASE LABEL • 6" x 6.75"

All UE items are preprinted on previously approved label stock

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

326

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

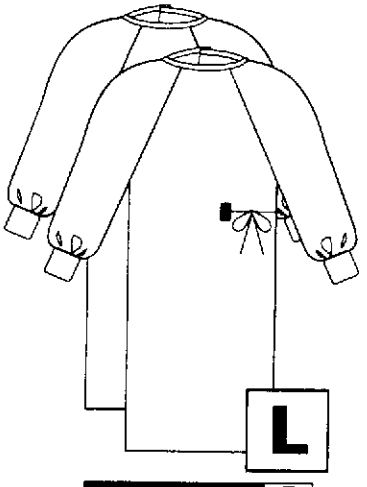
REF 95055
ULTRA Surgical Gown
Large
Two-Pack

ULTRA Surgical Gown
Large
Two-Pack
REF 95055

Kimberly-Clark REF 95055

ULTRA Surgical Gown, Large

with Polypropylene Fabric Two-Pack



AAMI Level 3

EVOLUTION

U.S. Patent Nos. 5,213,881; 5,271,882; 5,464,688

Disposable. Flame Resistant NFPA 702 Class 1

Made in [illegible]

CE 0086

LOT

Expiration Date

Sterile | Natural Rubber Latex Free

DRAFT

327

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

2-Label Set (Box and Package)
Representative for the ULTRA Film-Reinforced Surgical Gown

(for Reference No. 95431, XXL)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

ULTRA Film-Reinforced Surgical Gown, XX-Large

with Polypropylene Fabric

AAMI Level 4

30

(30 x 1)

Single Use Only

REF **95431** **15**

STERILE EO

Kimberly-Clark

LOT

Expiration Date

Made in Honduras

00000000000

CE 0086

1"

DRAFT

5/27/08 • THERMAL CASE LABEL • 6" x 6.75"

All items are proprietary to previously approved label shell

329

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

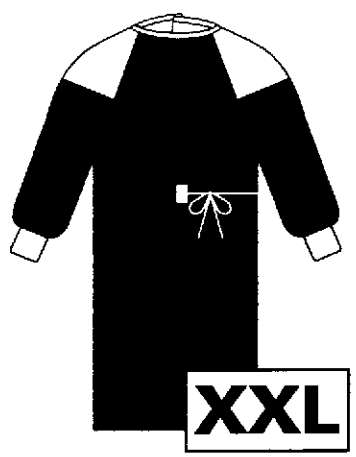
ULTRA Film-Reinforced
Surgical Gown
XX-Large
REF 95431

ULTRA Film-Reinforced
Surgical Gown
XX-Large
REF 95431

Kimberly-Clark REF 95431

ULTRA Film-Reinforced Surgical Gown, XX-Large

with Polypropylene Fabric



AAMI Level 4

Ma[illegible]Shield® Surgical Gowns pass ASTM F 1671 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration of Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Total System.

EVOLUTION® U.S. Patent Nos. 5,213,887; 5,271,883; 5,401,586

Disposable: Flame Resistant NFPA 702 Class 1

Made in Honduras

9/20/ Rev 03

CE 0086

LOT

Expiration Date

Sterile • Natural Rubber Latex Free

STERILE EO

2

Kimberly-Clark

DRAFT

Black is defined imprint

330

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

2-Label Set (Box and Package)
Representative for the ULTRA Film-Reinforced Specialty Surgical Gown

(for Reference No. 95511, L)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

6"

6.75"

Kimberly-Clark*

ULTRA Film-Reinforced Specialty Surgical Gown, Large with Polypropylene Fabric

AAMI Level 4

30

(30 x 1)

Single Use Only

REF **95511 35**

Kimberly-Clark

STERILE EO

LOT

Expiration Date

Made in Honduras

00000000000

CE 0086

1"

5/29/08 • THERMAL CASE LABEL • 6" x 6.75"

DRAFT

332

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-9647; Released by CDRH on 03-28-2016

REF 95511
ULTRA Film-Reinforced
Specialty Surgical Gown
Large

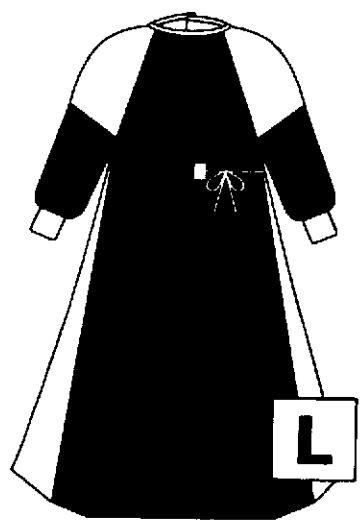
ULTRA Film-Reinforced
Specialty Surgical Gown
Large
REF 95511

Kimberly-Clark

REF 95511

ULTRA Film-Reinforced Specialty Surgical Gown, Large

with Polypropylene Fabric



AAMI Level 4

EVOLUTION®

Disposable, Flame Resistant NFPA 702 Class 1

CE 0086

LOT

Expiration Date

Sterile • Natural Rubber Latex Free

2

DRAFT

333

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118