



May 22, 2020

To: Manufacturers of Gowns and Other Apparel;
Healthcare Personnel;
Hospital Purchasing Departments and Distributors; and
Any Other Stakeholders

The U.S. Food and Drug Administration (FDA) is issuing this Emergency Use Authorization (EUA) in response to concerns relating to insufficient supply and availability of gowns and other apparel^{1,2} for use by healthcare personnel (HCP)³ as personal protective equipment (PPE)⁴ for use in healthcare settings in accordance with Centers for Disease Control and Prevention (CDC) recommendations to protect both HCP and patients from the transfer of SARS-CoV-2, the virus

¹ Gowns and other apparel are products intended to provide protection from the transfer of microorganisms and/or other contaminants in the use environment. Gowns and other apparel can be intended for medical or nonmedical purposes. Gowns and other apparel intended for a medical purpose are regulated by FDA under 21 CFR 878.4040 – Surgical apparel and 21 CFR 880.6265 – Examination gown. Depending on the intended use and the level of barrier protection provided, these devices can be classified as either class I (general controls) and exempt from the premarket notification requirements in 21 CFR Part 807 (“510(k) clearance”), Class II and exempt from premarket notification, or as class II requiring a submission of a premarket notification. As used in this letter, “intended for a medical purpose” means that the device is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease and, therefore, meets the definition of “device” set forth in section 201(h) of the FD&C Act.

² The gown products within the scope of this EUA-- gowns not intended for use as a “surgical gown” or “surgical isolation gown” may provide “minimal-to-low barrier protection,” meaning Level 1 or Level 2 protection or equivalent under the FDA-recognized standard ANSI/AAMI PB70: *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*.

³ HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, bodily fluids, excretions, etc.); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

⁴ FDA is issuing this EUA in light of availability concerns to help increase the availability of currently marketed and new gowns and other apparel for a medical purpose during the COVID-19 pandemic.

that causes Coronavirus Disease 2019 (COVID-19), in low or minimal risk level situations to prevent the spread of COVID-19^{5,6}.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.⁷ Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.⁸

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of certain gowns and other apparel, for use by HCP as PPE in health care settings, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of certain gowns and other apparel for use in healthcare settings in accordance with CDC recommendations to protect both HCP and patients from the transfer of SARS-CoV-2 in low or minimal risk level situations to prevent the spread of COVID-19 meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized gowns and other apparel worn by HCPs may be effective at preventing the

⁵ Please see FDA's letter to Health Care Providers entitled "Surgical Mask and Gown Conservation Strategies" (<https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-health-care-providers>) and CDC's "Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings" guidance (https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Finfection-control%2Fcontrol-recommendations.html) for more information.

⁶ In the circumstances of this public health emergency, it would not be feasible to require HCPs to seek to limit use of the gowns and other apparel covered by the EUA only to be used for patients with suspected or confirmed COVID-19; therefore, this authorization does not restrict use to such patients.

⁷ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 7316 (February 7, 2020).

⁸ U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 17335 (March 27, 2020).

transfer of microorganisms, bodily fluids, and particulate material in low or minimal risk situations by providing minimal-to-low barrier protection to HCP and patients to prevent the spread of COVID-19⁹, and that the known and potential benefits of gowns and other apparel for such use, outweigh the known and potential risks of such products; and

3. There is no adequate, approved, and available alternative to the emergency use of these gowns and other apparel.^{10,11}

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of certain gowns and other apparel for use by HCP as PPE in healthcare settings in accordance with CDC recommendations to protect both HCP and patients from the transfer of SARS-CoV-2 in low or minimal risk level situations to prevent the spread of COVID-19. This use is consistent with regulation of products under 21 CFR 878.4040 listed in Table 1.

Authorized Gowns and other Apparel

The types of gowns and other apparel¹² included in the scope of this EUA are those that are identified in the “Device Type” column in the table below.

Table 1. Gowns and Other Apparel

Classification Regulation	Device Type	Product Code ¹³	Class
21 CFR 878.4040	Conductive shoe and shoe cover	BWP	I (exempt)
21 CFR 878.4040	Operating-room shoes	FXW	I (exempt)
21 CFR 878.4040	Surgical apparel accessory	LYU	I (exempt)
21 CFR 878.4040	Non-surgical isolation gown	OEA	I (exempt)
21 CFR 878.4040	Operating-room shoe cover	FXP	I (exempt)
21 CFR 878.4040	Surgical helmet	FXZ	I (exempt)
21 CFR 878.4040	Surgical cap	FYF	I (exempt)

⁹ See footnote 6.

¹⁰ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

¹¹ There are not sufficient quantities of gowns and other apparel to meet the needs of the U.S. healthcare system. These articles of PPE are an integral part of patient care during the COVID-19 pandemic. Providing authorization for the introduction into interstate commerce of gowns and other apparel by manufacturers that do not customarily engage in the manufacture of medical devices helps meet the needs of the healthcare system. Providing HCP, who are on the forefront of the COVID-19 response, with sufficient PPE is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

¹² Face shields, face masks, surgical masks, and all particulate filtering respirators (filtering facepiece respirator, N95 respirator and surgical N95 respirator) are not included within the scope of this authorization. See <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations> for details on emergency use authorizations that may cover these products.

¹³ For more information see the Product Classification Database at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

This scope includes authorized gowns and other apparel that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system.¹⁴ Class I (reserved) and II devices that are not exempt from premarket review (i.e., 510(k) submission) are not included within the scope of this EUA (e.g., Product Code FYA - surgical gowns, FYC - surgical isolation gowns, etc.). Gowns intended to provide Level 3 or Level 4 liquid barrier protection or equivalent under the FDA-recognized standard ANSI/AAMI PB70: *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* are not included within the scope of this EUA.

Gowns and other apparel are authorized under this EUA when they are intended for use by HCPs in healthcare settings in accordance with CDC recommendations to protect both HCP and patients from the transfer of SARS-CoV-2 in low or minimal risk level situations to prevent the spread of COVID-19 and meet the following requirements:

1. The product is labeled accurately to describe the product as a “non-surgical gown,” or “non-surgical isolation gown,” or other apparel (as defined by Device Type in Table 1. above) as opposed to a “surgical gown” or “surgical isolation gown,” and includes a list of the body contacting materials (which does not include any drugs, biologics, nanoparticles, or antimicrobial/antiviral agents);
2. A gown must meet “minimal-to-low barrier protection,” meaning Level 1 or Level 2 protection or equivalent under the FDA-recognized standard ANSI/AAMI PB70: *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*;
3. The product includes labeling that accurately identifies: 1) the appropriate healthcare setting where the product is and is not to be used. For example, recommendations against gown use in a surgical setting or any other conditions where Level 3 or 4 protection is warranted; and 2) the flammability classification (Class I or Class II) or a warning statement against use of the products in the presence of high intensity heat source or flammable gas if Class I or Class II flammability is not demonstrated;
4. The product is labeled in such a manner that would not misrepresent the product’s intended use. For example, the labeling should not state or imply that the product is intended for antimicrobial or antiviral protection, infection prevention, or infection reduction. The product should not be misrepresented as a “surgical gown” or be labeled as having ANSI/AAMI PB70 Level 3 or Level 4 liquid barrier protection; and
5. The product labeling includes the intended use of the product for single use or reuse, with the appropriate instructions.

¹⁴ An “authorized decontamination system” means any decontamination system that has been issued an EUA. Authorized decontamination systems can be found on FDA’s Emergency Use Authorization webpage, available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

Manufacturers of gowns and other apparel that are used as described above and meet the above requirements (i.e., are within the Scope of Authorization, Section II) do not need to take any action, other than complying with the Conditions of Authorization (Section IV) to be authorized under this EUA. FDA's posting and public announcement of this EUA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>, serves as the gown and other apparel manufacturers' notification of authorization.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the gowns and other apparel as described within, and labeled and used consistent with the provisions of, the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that gowns and other apparel may be effective as described within, and used consistent with the provisions of, the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that gowns and other apparel as described within, and labeled and used consistent with the provisions of, the Scope of Authorization of this letter (Section II) meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the gowns and other apparel must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), gowns and other apparel authorized for use by HCPs in healthcare settings in accordance with CDC recommendations to protect both HCP and patients from the transfer of SARS-CoV-2 in low or minimal risk level situations and to prevent the spread of COVID-19.

III. Waiver of Certain FDA Requirements

I am waiving the following requirements for authorized gowns and other apparel during the duration of this EUA:¹⁵

- applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the authorized gowns and other apparel used in accordance with this EUA; and
- labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements (see Subpart B of 21 CFR Part 801), except that

¹⁵ Compliance with 21 CFR Part 806 (Reports of Corrections and Removals) and 21 CFR Part 807 (Registration and Listing) are not required under this EUA.

authorized gowns and other apparel must include the labeling elements specified in the Conditions of Authorization (Section IV).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions to this authorization:

Manufacturers and Distributors of Authorized Products

- A. Manufacturers and distributors must make available the following content in the labeling accompanying authorized gowns and other apparel:
- The product must be labeled accurately to describe the product as a non-surgical gown, non-surgical isolation gown or other apparel (as identified by Device Type in Table 1) for medical purposes and a list of the body contacting materials (which does not include any drugs, biologics, nanoparticles, or antimicrobial/antiviral agents);
 - A gown must be labeled accurately to describe the barrier protection, and such statements are for only minimal or low barrier protection (ANSI/AAMI PB70 barrier protection Level 1 or Level 2);
 - The product must be labeled accurately to identify the appropriate healthcare setting where the product is and is not to be used. For example, recommendations against gown use in a surgical setting or any other conditions where Level 3 or 4 protection is warranted;
 - The product must be labeled accurately to identify the flammability classification (Class I or Class II) or include a warning statement against use of the products in the presence of high intensity heat source or flammable gas if Class I or Class II flammability is not demonstrated;
 - The product must be labeled to include a description of the product as intended for either single use or reuse.
 - If a device is for single use only, the labeling must instruct the user to discard after use per healthcare facility procedures.
 - If a device is intended for reuse, the labeling must include validated instructions for cleaning and disinfection or cleaning and sterilization in compliance with Occupational Safety and Health Administration (OSHA) standards. The manufacturer must make sure i) the material compatibility of the gown with the proposed cleaning detergents, chemical disinfectants, or sterilization sterilants; and ii) the reprocessing residues are not a toxicity risk concern. The labeling must include clear instructions to the end user regarding how to inspect the gown quality after the proposed reprocessing and when the gown should be discarded.

Manufacturers must make available all labeling in English, to each end user facility (e.g., each hospital) that receives the authorized gowns and other apparel and may include authorized labeling with each individual authorized product.

- B. Manufacturers and distributors of authorized products shall ensure the labeling does not state or imply that the product is intended: 1) for antimicrobial or antiviral protection, infection prevention, or infection reduction; 2) as a surgical gown or be labeled as having ANSI/AAMI PB70 Level 3 or Level 4 liquid barrier protection.
- C. Manufacturers and distributors must make available instructions for recommended cleaning and disinfection or cleaning and sterilization materials and processes, if applicable, for their authorized product(s). Manufacturers must make available these instructions, if applicable, to each end user facility (e.g., each hospital) that receives the authorized gowns and other apparel and may include such instructions on each individual authorized product.
- D. Manufacturers will have a process in place for reporting adverse events of which they become aware to FDA under 21 CFR Part 803. Adverse events of which the manufacturer becomes aware will be reported to FDA. See FDA's webpage "[Medical Device Reporting \(MDR\): How to Report Medical Device Problems](#)"¹⁶ for reporting requirements and procedures.
- E. Manufacturers and distributors will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.
- F. Through a process of inventory control, manufacturers and distributors will maintain records of the entities to which they distribute the gowns and other apparel and the numbers of each such product they distribute.
- G. Manufacturers and distributors are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

Conditions Related to Advertising and Promotion

- H. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized gowns and other apparel shall be consistent with the labeling elements listed in Section II of this EUA, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.
- I. No descriptive printed matter, including advertising or promotional materials, relating to the use of the authorized gowns and other apparel may represent or suggest that such product is safe or effective for the prevention or treatment of COVID-19.
- J. All descriptive printed matter, including advertising and promotional materials, relating to the use of the product shall clearly and conspicuously state that

¹⁶ <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

- The product has not been FDA cleared or approved;
- The product has been authorized by FDA under an Emergency Use Authorization (EUA) for use as PPE in healthcare settings by HCP as they may help protect HCP and/or patients from the transfer of the SARS-CoV-2 virus in low or minimal risk level situations to prevent the spread of COVID-19.
- This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak, under Section 564(b)(1) of the Act, 21 USC 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration