

K143182

FDA CDRH DMC

NOV 06 2014

Received

November 3, 2014

FDA/CDRH  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**RE: 510(k) Notification (21 CFR 807.90(e)).  
Traditional 510(k)  
Speedicath Compact Male**

To Whom It May Concern:

Coloplast A/S hereby submits this Traditional Premarket Notification 510(k) in duplicate to request clearance of the Speedicath Compact Male device. In lieu of one paper copy, Coloplast is providing an electronic version copied to CD-ROM per FDA guidance "eCopy Program for Medical Device Submissions" dated October 10, 2013. The electronic copy is an exact duplicate of the paper copy.

Speedicath Compact Male is classified as a Class II urological catheter and accessories per 21 CFR 876.5130, Product Code GBM. The appropriate Review Panel is Gastroenterology/Urology.

Medical Device User Fee Cover Sheet (Form OMB 0910-511) with Payment Identification Number **MD6078292** is attached to this cover letter.

Coloplast considers the existence and contents of this submission to be confidential and exempt from public disclosure.

Please contact me for questions or if you need further information.

Best regards,



Brian E. Schmidt  
Regulatory Affairs Manager  
Coloplast Corporation  
1601 West River Road N  
Minneapolis, MN 55411 USA

Office: (612) 302-4987  
Mobile: (612) 968-9567  
Fax: (612) 287-4138  
Email: [usb@coloplast.com](mailto:usb@coloplast.com)

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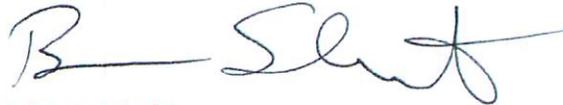
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Please contact me for questions or if you need further information.

Best regards,

A handwritten signature in black ink, appearing to read "B. Schmidt", with a long horizontal line extending to the left.

Brian E. Schmidt  
Regulatory Affairs Manager  
Coloplast Corporation  
1601 West River Road N  
Minneapolis, MN 55411 USA

Office: (612) 302-4987  
Mobile: (612) 968-9567  
Fax: (612) 287-4138  
Email: [usb@coloplast.com](mailto:usb@coloplast.com)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
---	--

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/mdufma/cover sheet.html>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  COLOPLAST MANUFACTURING US LLC 1601 WEST RIVER ROAD N MINNEAPOLIS MN 55411 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****5281	2. CONTACT NAME Angela Kilian 2.1 E-MAIL ADDRESS usaby@coloplast.com 2.2 TELEPHONE NUMBER (include Area code) 612-287-4236 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 612-287-4138
---	---

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm>)

Select an application type:

<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 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  NO, I am not a small business

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

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/cdrh/mdufma> for additional information)

6. 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

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

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

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

7. 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  NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes 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 the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

30-Oct-2014

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission 03-NOV-2014	User Fee Payment ID Number <b>(b)(4)</b>	FDA Submission Document Number (if known) TBD
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**SECTION A TYPE OF SUBMISSION**

<p><b>PMA</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<p><b>PMA &amp; HDE Supplement</b></p> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<p><b>PDP</b></p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<p><b>510(k)</b></p> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<p><b>Request for Feedback</b></p> <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
<p><b>IDE</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p><b>Humanitarian Device Exemption (HDE)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p><b>Class II Exemption Petition</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Evaluation of Automatic Class III Designation (De Novo)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Other Submission</b></p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Coloplast A/S	Establishment Registration Number (if known) 2125050		
Division Name (if applicable) Coloplast Corp.	Phone Number (including area code) 612-302-4987		
Street Address 1601 West River Road North	FAX Number (including area code) 612-287-4138		
City Minneapolis	State / Province MN	ZIP/Postal Code 55411	Country USA
Contact Name Brian Schmidt			
Contact Title Regulatory Affairs Manager		Contact E-mail Address usb@coloplast.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 Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

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

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION D2 REASON FOR APPLICATION - IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION D3 REASON FOR SUBMISSION - 510(k)**

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	GBM	2		3	
4		5		6	
7		8		9	
				<input type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 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	K121458	Speedicath Compact Male Set	Coloplast A/S
2			
3			
4			
5			
6			

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name  
 Urological Catheter with Accessories

	Trade or Proprietary or Model Name for This Device	Model Number
1	Speedicath Compact Male	1 28692
2		2
3		3
4		4
5		5

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

1	2	3	4	5	6
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 GBM	C.F.R. Section (if applicable) 21 CFR 876.1530 Urological Catheter and accessories	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Gastroenterology/Urology		

Indications (from labeling)

SpeediCath Compact Male is indicated for use by patients with urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain. The catheter is for male patients.

**Note:** Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
--	--	---

Company / Institution Name Coloplast A/S	Establishment Registration Number 9610694
---	--

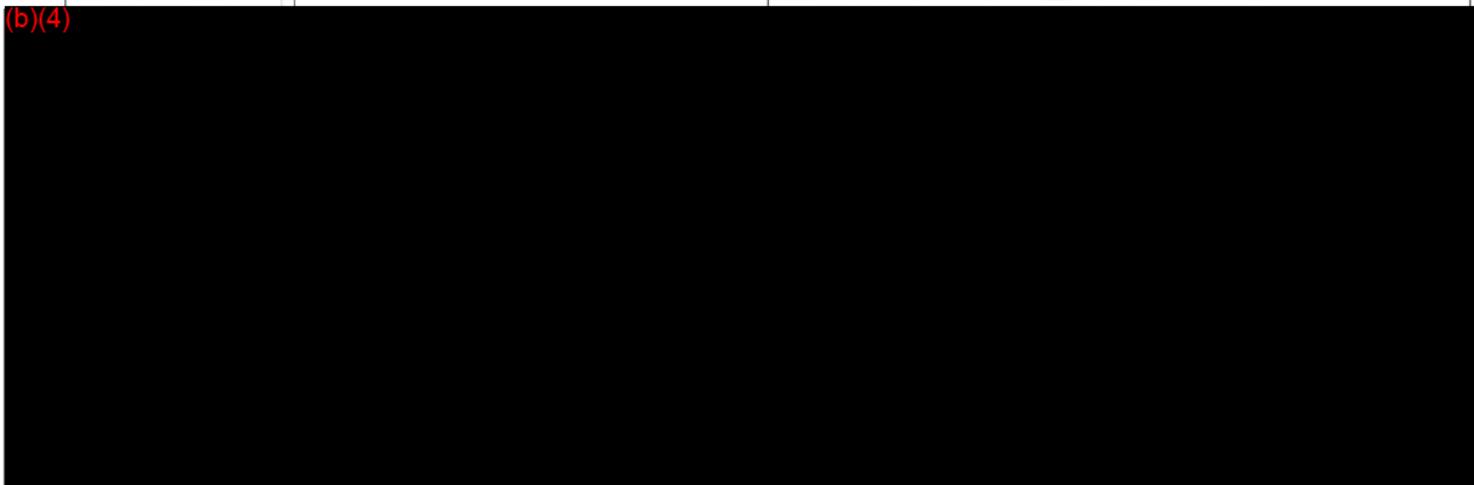
Division Name <i>(if applicable)</i> Coloplast A/S	Phone Number <i>(including area code)</i> 612-302-4987
---	---

Street Address Holtedam 1	FAX Number <i>(including area code)</i> 612-287-4138
------------------------------	---

City Humbleback	State / Province	ZIP Code 3050	Country Denmark
--------------------	------------------	------------------	--------------------

Contact Name Brian Schmidt	Contact Title Regulatory Affairs Manager	Contact E-mail Address usb@coloplast.com
-------------------------------	---	---

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
--	--	---



(b)(4)

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
---	--	--

Company / Institution Name	Establishment Registration Number
----------------------------	-----------------------------------

Division Name <i>(if applicable)</i>	Phone Number <i>(including area code)</i>
--------------------------------------	---

Street Address	FAX Number <i>(including area code)</i>
----------------	---

City	State / Province	ZIP Code	Country
------	------------------	----------	---------

Contact Name	Contact Title	Contact E-mail Address
--------------	---------------	------------------------

**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			Standards Forms Provided in Appendix 2 of this 510(k) for a summary of the standards referenced in this submission.		
2					
3					
4					
5					
6					
7					

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
 Food and Drug Administration  
 Office of Chief Information Officer  
 Paperwork Reduction Act (PRA) Staff  
 1350 Piccard Drive, Room 400  
 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.*



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 Coloplast A/S	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 11/03/2014
3. ADDRESS (Number, Street, State, and ZIP Code) <b>(b)(4) Third Party Information</b>	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 612-302-4987 (Fax) 612-287-4138

**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)

Common name: Urological Catheter and accessories  
Models: \_\_\_\_\_

Classification names: 21 CFR 876.1530 Gastroenterology-Urology  
28692

Trade/proprietary name: Speedicath Compact Male

**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) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Brian Schmidt (Title) Regulatory Affairs Manager
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 1601 West River Road North Minneapolis, MN 55411	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 612-302-4987 (Fax) 612-287-4138
	15. DATE OF CERTIFICATION 11/03/2014



## **SpeediCath Compact Male**

510(k) Premarket Notification

November 03, 2014

Coloplast Corp  
1601 West River Road North  
Minneapolis, MN 55411  
USA

**SpeediCath Compact Male**

510(k) Premarket Notification

**Applicant:**

Coloplast Corp  
1601 West River Road North  
Minneapolis, MN 55411  
USA

**Name of Contact Person:**

Brian E. Schmidt  
Regulatory Affairs Manager  
Coloplast Corp  
1601 West River Road  
Minneapolis, MN 55411  
USA  
Office: (612) 302-4987  
Mobile: (612) 968-9567  
Fax: (612) 287-4138  
E-mail: [usb@coloplast.com](mailto:usb@coloplast.com)

**Manufacturer:**

Coloplast A/S  
Holtedam 1  
DK-3050 Humlebaek  
Denmark

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**Statement of Indications for Use**

510(k) Number (if known): Not known

Device Name: **SpeediCath** Compact Male

Indications for Use:

**SpeediCath** Compact Male is indicated for use by patients with urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain. The catheter is for male patients.

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X   OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

**Truthful and Accurate Statement**

I certify that, in my capacity as Manager, Regulatory Affairs of Coloplast Corp, I believe to the best of my knowledge that all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted.



\_\_\_\_\_  
Brian E. Schmidt

11-03-2014

Date

\_\_\_\_\_  
Pre-market Notification (510(k)) Number

## **General Information**

### **Device Name:**

Common Name: **SpeediCath** Compact Male  
Proprietary Name: **SpeediCath** Compact Male  
Classification Name: 21 CFR 876.5130 Gastroenterology-Urology Devices  
Classification: Class II  
Product code: GBM  
Panel: Gastroenterology/Urology

### **Applicant and Distributor Name and address:**

Coloplast Corp  
1601 West River Road North  
Minneapolis, MN 55411  
USA

### **Official Correspondent Name and Address:**

Angela Kilian  
Head of Regulatory Affairs  
Coloplast Corp  
1601 West River Road North  
Minneapolis, MN 55411  
USA

### **Submission Contact Name and Address:**

Brian E. Schmidt  
Regulatory Affairs Manager  
Coloplast Corp  
1601 West River Road  
Minneapolis, MN 55411  
USA  
Office: (612) 302-4987  
Mobile: (612) 968-9567  
Fax: (612) 287-4138  
e-mail: usbes@coloplast.com

### **Manufacturer Name and Address:**

Coloplast A/S  
Holtedam 1  
DK-3050 Humlebaek  
Denmark

### **Establishment Registration No.:**

9610694

**Manufacturing Site Name and Address**

Coloplast A/S – Mordrup Site  
Aa. Louis-Hanses Alle 15  
Espergaerde, Region Hovestaden  
3060 Denmark

**Establishment Registration No.:**

Registration Number is pending

**Performance Standards:**

ASTM F 623-99, ASTM D 1894-11, EN 1616, EN 1617 and EN 1618

**Proposed Indications:**

**SpeediCath** Compact Male is indicated for use by patients with urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain. The catheter is for male patients only.

**Predicate Device:**

The **SpeediCath** Compact Set Male was cleared on October 1, 2012 (510(k) number K121458), and the device is a modification of the **SpeediCath** Compact Male (subject to this 510(k) submission).

The **SpeediCath** Compact Male is substantially equivalent in performance, indications, design and materials to **SpeediCath** Compact Set Male.

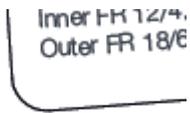
**Reference device:**

**SpeediCath** Compact Female cleared on November 9, 2002 under premarket notification number K072808. For this 510(k) application this product will be referred to as **SpeediCath** Compact Female.

**Device Labeling**

Proposed labeling for **SpeediCath** Compact Male.

**Primary Package Label:**



Inner FR 12/4,  
Outer FR 18/6

Illustration of how the label will look like on the device:



The following will be laser engraved on the bottom of the tube (on the plug) during production:

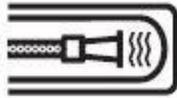
Lot # xxxxxxxx

Use By yyyy-mm-dd (year-month-date)



**Retail Box Label:**

**SpeediCath®  
28692**



**Compact**

Urinary catheter for intermittent catheterization.

Ready to use coated catheter.

Nelaton

Rx Only

**30 pcs**

FR 12/4.0-18/6.0 mm **Male**

**EAN 13 Barcode  
000000000000**



Coloplast Corp.  
1601 West River Road  
North  
Minneapolis  
MN 55411 USA  
www.coloplast.us  
Tel. 1-800-533-0464

**Country of origin: HU**

 yyyy-mm

 yyyy-mm

**LOT** 1234567

**128 Barcode  
000000000000**

**Device Shipper Box Label:**

**REF 2869201400**

**SpeediCath® Compact**

Urinary catheter for intermittent catheterization.  
Ready to use coated catheter.  
Nelaton  
Rx Only

Coloplast Corp.  
1601 West River Road North  
Minneapolis  
MN 55411 USA  
www.coloplast.us  
Tel. 1-800-533-0464

**10 x 30 pcs**

FR 12/4.0-18/6.0 mm **Male**

 yyyy-mm  
 yyyy-mm  
**LOT** 1234567  
**Country of origin: HU**

 Coloplast A/S  
Holtedam 1  
3050 Humlebaek  
Denmark

  **STERILE R**

EAN 13  
Barcode  
0000000000000

128 Barcode  
0000000000000

## Instructions for Use:

**SpeediCath® Compact**  
Male



### How to use

SpeediCath Compact is developed for drainage of the bladder by intermittent catheterisation.

This Compact catheter is designed especially for men. It is part of the unique SpeediCath family with its main focus being hygiene and safety. SpeediCath consists of a coated, ready-to-use catheter supplied in saline solution.

Start by washing your hands and the area around the urethral orifice. It is important to avoid transferring bacteria from your hands to the catheter.

Make sure you are completely ready to proceed with catheterisation before you open the packaging. Complete the catheterisation without undue delay and remove the catheter upon emptying the bladder.



1 - 2) Hold the catheter vertically so the lid points upwards and open the packaging by twisting the lid. Make sure lid is kept within reach.



3) Pull the white connector upwards to release the catheter. The catheter is released when you hear a "click" and it is now ready to be used. Avoid touching the surface of the catheter – only touch the white connector and be sure to not to bend the catheter.



4) If possible, empty the water from the packaging in a toilet or sink before catheterisation.



5) Lift the penis with one hand to straighten out the urethra. Do not squeeze the penis during catheterisation.

Insert the catheter slowly into the urethra until urine starts to flow. Hold onto the connector during the entire catheterisation, to ensure the catheter stays in the urethra.

When urine stops flowing, pull the catheter out about 1-2 cm. If urine starts flowing again, wait until it stops. Then pull the catheter out 1-2 cm again. When your bladder is empty remove the catheter.



6) After use the catheter can be pushed back into the packaging using a little force. Put the lid back on and discard.

### Instructions for use

23315975 Version 1

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Manufacturer: Coloplast A/S  
Høldedam 1, 3050 Humlebaek, Denmark  
Distributed by: Coloplast Corp., 1601 W. River Rd. N, Minneapolis, MN 55411 USA  
For customer service or to return product, please call (800) 258 3476 or (612) 337 7800  
Distributed by: Information about local distributor is found in the Instructions For Use.  
Fabricante: Coloplast A/S Høldedam 1 3050 Humlebaek Denmark

Product Evaluation  
For customer service or to return product, please call: 1-800-533-0464 in USA.  
Rx only  
Evaluación del Producto  
Para servicio al cliente o para devolver el producto, llame a: 1-800-533-0464 en EE.UU.

### Indication

Urinary catheter for intermittent use.

The catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing the urine to drain.

### Information

Coloplast accepts no liability for any injury or loss that may arise if this product is used in a manner contrary to Coloplast's current recommendations.

The catheter can be exposed to extreme temperatures (below 0°C and up to 60°C) for up to 24 hours without the catheter being damaged.

The solution in which the catheter is stored is harmless. However, the solution may stain.

Catheterization should take place as quickly as possible after opening the package. The catheter should always be removed when the bladder has been emptied.

### Cautions

Do not use if package is damaged  
Contact your health care professional before you perform self-catheterization for the first time.

Contact your health care professional if you:

- have been diagnosed with urethral strictures.
  - experience that the catheter does not drain the bladder the way you are used to.
  - experience symptoms such as fever, discomfort when emptying the bladder, a frequent urge to urinate or blood in the urine.
- Federal (USA) law restricts this device to sale by or on the order of a physician. Inspect the catheter before use.

### Warning

Reusing this single-use product may create a potential harm to the user. Reprocessing, washing, disinfection, and/or sterilization may compromise product characteristics, causing additional risk of physical harm to or infection of the user.

### Symbols



Do not use if package is damaged



Sterilized using irradiation



Consult instructions for use



Do not re-use



Use-by date



Batch code



Date of manufacture



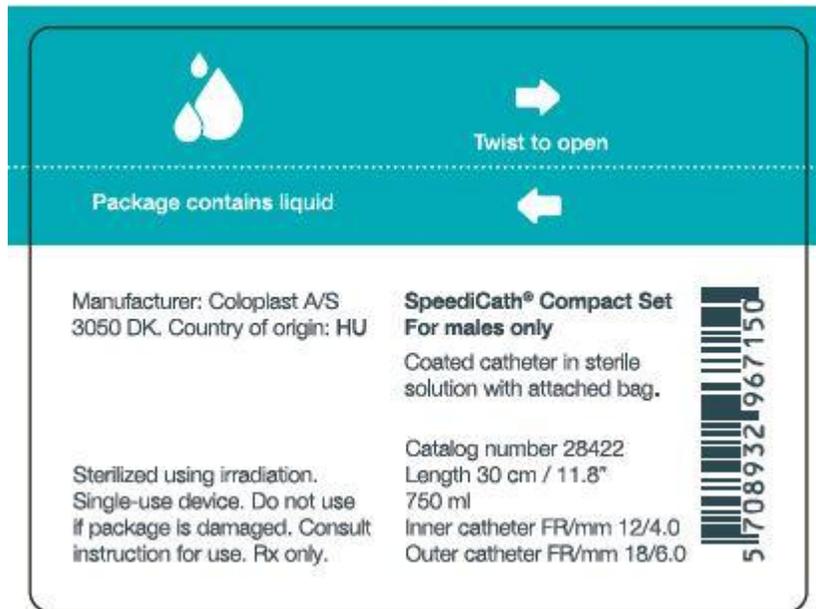
Manufacturer: Coloplast A/S  
Høldedam 1, 3050 Humlebaek, Denmark

## Predicate device labeling

The following labels are examples of predicate labels and are representative of all the available sizes.

Labeling of **SpeediCath Compact Set Male K121458**

### Product label:



### Retail box labels\*:

## SpeediCath® Compact Set

**28422**



Urinary catheter with attached bag for intermittent catheterization.

Ready to use coated catheter.

Nelaton

Rx Only

Length: 11.8 in, Vol 750 ml

**20 pcs**

Inner catheter CH/FR 12/4.0 mm

Outer catheter CH/FR 18/6.0 mm **Male**

**BARCODE**  
**000000000000**

Manufacturer: Coloplast A/S Høltedam 1, 3050 Humlebaek, Denmark, Consult Instruction for Use, Do Not Reuse, Sterilized Using Irradiation, Keep Away From Sunlight, Store at room temperature and in a dry location

Shipper box label\*:

# No.2842211400 SpeediCath® Compact Set

Coloplast Corp.  
1601 West River Road North  
Minneapolis  
MN 55411

Urinary catheter with attached bag for intermittent catheterization.  
Ready to use coated catheter.  
Nelaton  
Rx Only  
Length: 11.8 in, Vol 750 ml

USA  
www.us.coloplast.com  
Tel.1-800-533-0464

**3 x 20 pcs**

Date of Manufacture *yyyy-mm*

Inner catheter CH/FR 12/4.0 mm

Use By *yyyy-mm*

Outer catheter CH/FR 18/6.0 mm **Male**

Batch Code 1234567

Manufacturer: Coloplast A/S Høtveddam 1, 3050  
Humblebaek, Denmark, Consult Instruction for  
Use, Do Not Reuse, Sterilized Using  
Irradiation, Keep Away From Sunlight, Store at  
room temperature and in a dry location



Horizontal Storage

**EAN 13 Barcode**  
0000000000000

Country of Origin: DK

**128 Barcode**  
0000000000000

**Male**

liquid inside may leave stains when in contact with clothing. Otherwise the liquid is harmless.

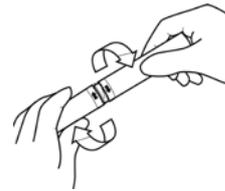
Coloplast accepts no liability for any injury or other loss that may arise if this product is used in a manner contrary to Coloplast's current recommendations.

Manufacturer : Coloplast A/S 3050 DK  
 Distributed by: Coloplast Corp., Minneapolis, MN, 55411, USA  
 23313501 V4.0b The Coloplast logo is a registered trademark of Coloplast A/S.  
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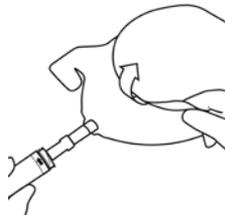
**How to use SpeediCath Compact Set**



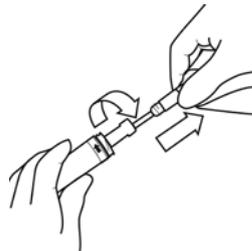
**1 Opening / Preparation**  
 Start by washing your hands and the area around the urethral orifice. It is important to avoid transferring bacteria from your hands to the catheter.



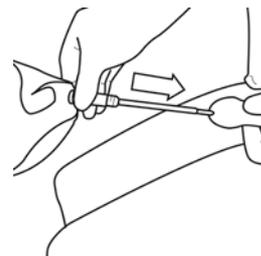
Twist and remove the cover



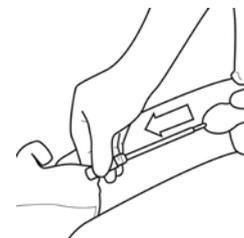
Unfold the bag



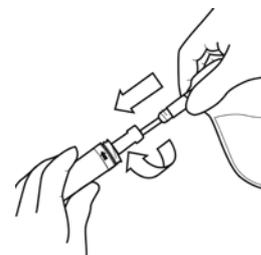
Twist and pull the catheter out



**2 Application / Insertion**  
 Lift the penis with one hand to straighten out the urethra. Insert the catheter into the urethra until urine starts to flow



**3 Removal**  
 When urine stops flowing, pull the catheter out about 1-2 cm. If urine starts flowing again, wait until it stops. Then pull the catheter out 1-2 cm again. When your bladder is empty remove the catheter.



**4 Emptying**  
 Reseal the catheter by twisting it back into the packaging

**Warnings**

Reuse of this single use product may create a potential risk to the user. Reprocessing, cleaning, disinfection and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient.

**Cautions**

Self-catheterization is a common and reliable procedure. However, prior to performing self-catheterization it is important to consult a medical professional for guidance and follow these instructions carefully.

In case of urinary tract infection with symptoms such as fever, discomfort when emptying the bladder, a frequent urge to urinate or blood in the urine, contact your physician/nurse.

If you have been diagnosed with urethral strictures consult your health care professional.

Do not use if package or seal is damaged. Do not re-sterilize.

Keep away from sunlight. Store products horizontally at room temperature and at dry conditions. Exposure to extreme temperatures (-20°C to 60°C) for up to 24 hours will not damage the product.

Federal law restricts this device to sale by or on the order of a physician.

**Indications**

The catheter is sterile and for intermittent use only.

SpeediCath Compact Set is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

This device is intended for males only.

**Information**

This product is a coated catheter in sterile solution with attached bag.

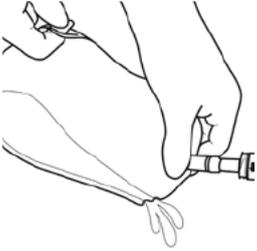
Complete catheterization without undue delay and remove the catheter upon emptying the bladder.

Care should be taken when opening and handling the product as the

Open the urine bag by tearing off the tap



Empty the bag into the toilet and dispose the catheter and bag in household rubbish



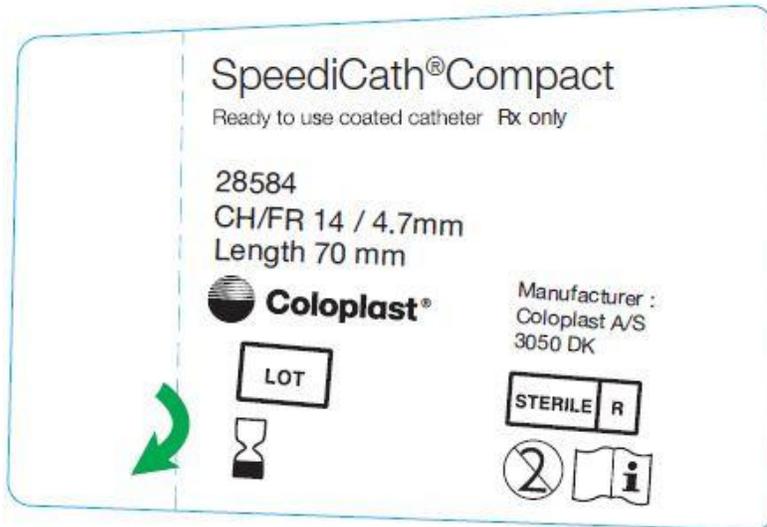
Symbol	
<b>WO</b>	Work order. Production number identifying the packaging of a specific order. (LOT-number relates to production run).
	Use By
	Batch Code
	Date of Manufacture
	Consult Instruction for Use
	Do Not Reuse
	Sterilized using irradiation
	Do Not Use if Package is Damaged
Prescription device	Caution: US Federal law restricts this device to sale by or on the order of a physician. Rx Only
	Keep Away From Sunlight
	Recycle

### Reference device labeling

The following labels are examples of reference labels and are representative of all the available sizes.

Labeling of **SpeediCath Compact Female K072808**

### Product label:



### Retail Box Label:

**SpeediCath®  
28584**



### Compact

Urinary catheter for intermittent catheterization.  
Ready to use coated catheter.  
Nelaton  
Rx Only  
Not made with natural rubber latex.

**30 pcs**  
FR 14/4.7 mm **Female**

**EAN 13 Barcode**  
**000000000000**



Coloplast Corp.  
1601 West River Road  
North  
Minneapolis  
MN 55411  
USA  
www.us.coloplast.com  
Tel.1-800-533-0464

### Country of origin: HU

yyy-mm

yyy-mm

LOT 1234567

**EAN 13 Barcode**  
**000000000000**

**Shipper label:**

**No.2858401400**  
**SpeediCath® Compact**

Urinary catheter for intermittent catheterization.

Ready to use coated catheter.

Nelaton

Not made with natural rubber latex.

Rx Only

**Country of origin: HU**

**10 x 30 pcs**

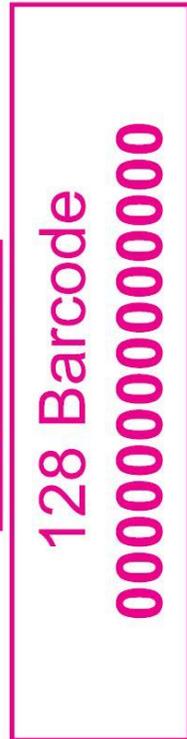
**CH/FR 14/4.7 mm Female**

Date of Manufacture **yyyy-mm**

Use By **yyyy-mm** Batch Code **1234567**

Manufacturer: Coloplast A/S Høltedam 1, 3050 Humlebaek, Denmark,  
Consult Instruction for Use, Do Not Reuse, Sterilized Using Irradiation,  
Keep Away From Sunlight, Store at room temperature and in a dry location

Coloplast Corp.  
1601 West River Road  
North  
Minneapolis  
MN 55411  
USA  
[www.us.coloplast.com](http://www.us.coloplast.com)  
Tel.1-800-533-0464



SpeediCath Compact & SpeediCath Compact Plus<sup>1</sup>  
 Ready to use coated catheter.  
 Urinary catheter for intermittent use.

## How to use SpeediCath Compact

SpeediCath Compact is designed to be used whilst sitting on the toilet.

Begin by washing your hands and the area around the urethral opening. It is important to avoid transferring bacteria from your hands or genitalia to the catheter. SpeediCath Compact is immersed in a sterile saline solution. Before you attempt to open the catheter, ensure that you are completely ready to proceed with the catheterisation.

1. Hold the product vertically with the grip pointing downward.
2. Break the seal by gently twisting the two sections of the tube in opposite directions.
3. Slowly pull apart the outer and inner tube until they lock in the fully extended position. The outer tube is the catheter handle. The catheter rests inside the inner tube.
4. To release the catheter, hold the outer tube firmly and remove the inner tube by gently twisting and pulling it off. The inner tube may be discarded or emptied and retained for discreet disposal later. The catheter is now ready for use.



Inspect the catheter before use. Do not use the product if the device or pack-aging is damaged.

5. Part the labia with one hand to expose the urethral orifice. Use your other hand to insert the catheter gently into the urethra approx. 2 cm at a time. Just before the catheter reaches the bladder, you may feel slight resistance from the sphincter.

Continue to insert the catheter into the urethra until urine starts to flow.

6. When the urine stops flowing, ease out the catheter 1-2 cm. If the flow of urine restarts, wait a few seconds before easing out the catheter another 1-2 cm. When the bladder is completely empty, slowly remove the catheter and dispose of it hygienically.

### Instructions for use

Manufacturer:  
 Coloplast A/S  
 Holtedam 1  
 3050 Humlebaek  
 Denmark  
 Distributed by: Coloplast Corp., Minneapolis, MN, 55411, USA  
 23313796 Version 2  
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### Indication

SpeediCath Compact is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain. The catheter is for female patients only.

### Information

Coloplast accepts no liability for any injury or loss that may arise if this product is used in a manner contrary to Coloplast's current recommendations.  
 The catheter can be exposed to extreme temperatures (below 0°C and up to 60°C) for up to 24 hours without the catheter being damaged.  
 The solution in which the catheter is stored is harmless. However, the solution may stain. Catheterization should take place as quickly as possible after opening the package. The catheter should always be removed when the bladder has been emptied.

### Caution

Do not use if package is damaged.  
 Contact your health care professional before you perform self-catheterization for the first time.  
 Contact your health care professional if you:  
 - experience that the catheter does not drain the bladder the way you are used to.  
 - experience symptoms such as fever, discomfort when emptying the bladder, a frequent urge to urinate or blood in the urine.  
 Federal (USA) law restricts this device to sale by or on the order of a physician.  
 Inspect the catheter before use.

### Warning

Re-use of the single use product may create a potential harm to the user. Reprocessing, washing, disinfection, and sterilization may compromise product characteristics, causing additional risk of physical harm to or infection of the user.

### Symbol



Do not use if package is damaged.



Sterilized Using Irradiation



Consult Instructions for Use



Do Not Reuse



Use-by date



Batch Code



Date of manufacture.



Coloplast A/S  
 Holtedam 1  
 3050 Humlebaek  
 Denmark  
 Manufacturer: Coloplast A/S Holtedam 1, 3050 Humlebaek, Denmark

### Product Evaluation

For customer service or to return product, please call:  
 1-800-533-0464 in USA.

Prescription device

Caution: US Federal law restricts this device to sale by or on the order of a physician. Rx Only

## Substantial Equivalence Comparison

### Statement of equivalence

The intended use for **SpeediCath** Compact Male is the same as for **SpeediCath** Compact Set Male (K121458). Coloplast considers **SpeediCath** Compact Male to be substantially equivalent to the predicate device.

**SpeediCath** Compact Male and the predicate device are catheters for intermittent use with hydrophilic coating. They are both sold sterile and as single use devices.

The hydrophilic coating, which is in direct contact with the urethra, is made of the (b)(4) (b)(4) material in both **SpeediCath** Compact Male and the predicate device. Both catheters are (b)(4).

The main difference between **SpeediCath** Compact Male and the predicate device is the packaging configuration and visual appearance. **SpeediCath** Compact Male does not have a pre-attached urine collection bag like the predicate device. The **SpeediCath** Compact Male packaging configuration has the same ready to use features as the predicate, and is packaged in discrete containers. Same as the predicate device, **SpeediCath** Compact Male is short in storage and is extended to its full length due to the telescopic extension of the catheter. The telescopic extension mechanism is identical between the two catheters.

Both **SpeediCath** Compact Male and the predicate device are in one size (FR 12/18) only.

The idea behind **SpeediCath** Compact Male is to have a catheter that is tailored to meet the special needs and anatomy of male catheter users and to provide an easier and more discrete product.

The length of **SpeediCath** Compact Male catheter in its full length is the same as the predicate device (30 cm without connector). When **SpeediCath** Compact Male is not fully extended and in its primary packaging, the length is 19 cm. This makes the product discrete.

The European standard, EN 1616, sets a minimum of 36 cm for the total length (catheter and connector) of catheters without balloons, but does not set any requirements for the catheter length alone (effective drainage length)<sup>1</sup>.

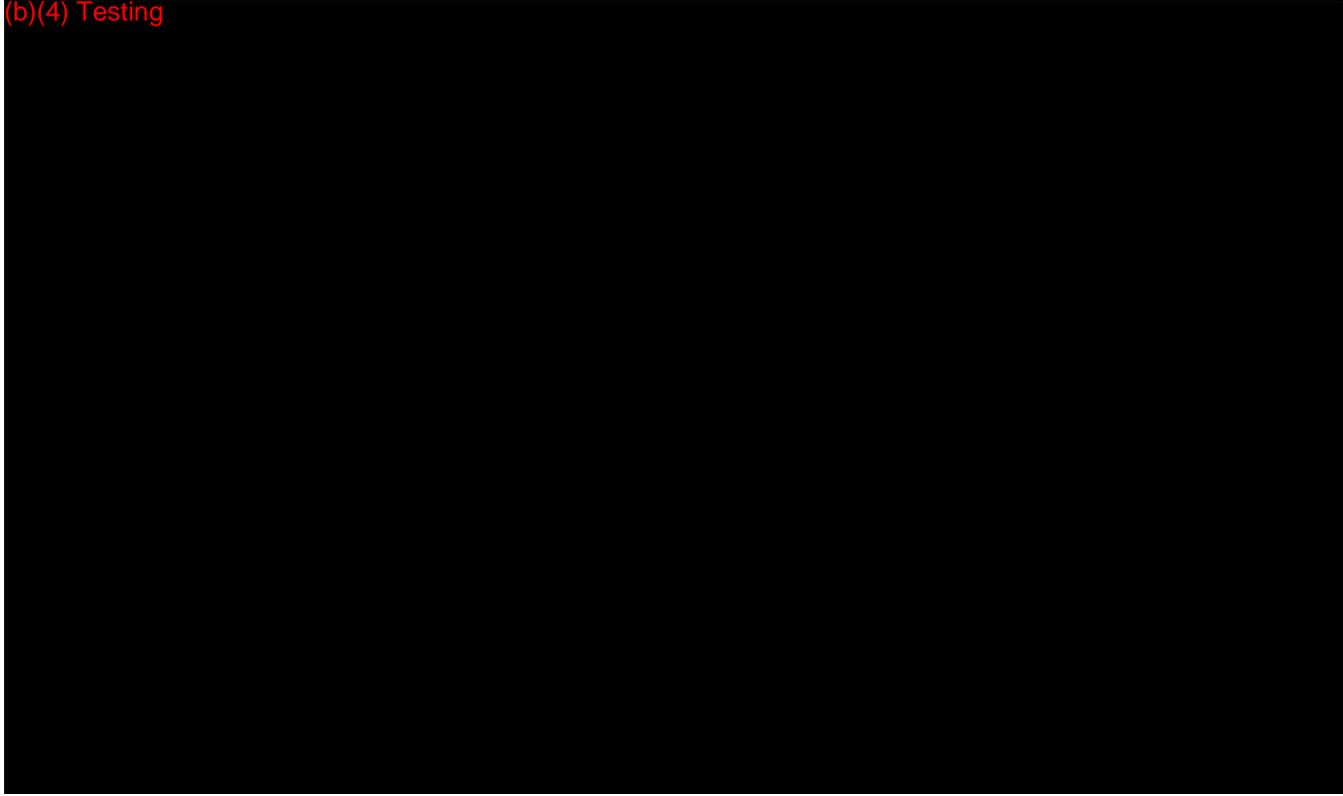
Gray's anatomy describes the male urethral length as 18-20 cm long<sup>2</sup>. Furthermore, Kohler et al. performed an investigation with 109 men showing that the male urethral length is 22.3±2.4 cm, ranging from 15-29 cm<sup>3</sup>.

<sup>1</sup> Sterile urethral catheters for single use. European Standard EN 1616. CEN European Committee for Standardization, Brussels 1997. Ref. No. EN 1616: 1997 E.

<sup>2</sup> Gray's Anatomy Fortieth Edition 2008.

<sup>3</sup> Kohler TS, Yadven M, Manvar A, Liu N, Monga M. The Length of the Male Urethra. International Braz J Urol. Vol. 34 (4): 451-456, July – August, 2008.

(b)(4) Testing



As seen in the tabular presentation below and the above discussion, **SpeediCath** Compact Male does not raise any new questions about safety and effectiveness and Coloplast considers **SpeediCath** Compact Male to be substantially equivalent to the predicate device.

(b)(4)



## Comparison Chart for Substantial Equivalence

	<b>Predicate Device SpeediCath Compact Set - male</b>	<b>This 510(k) SpeediCath Compact – male</b>	<b>Reference Device SpeediCath Compact - female</b>
Manufacturer	Coloplast	Same	Same
510(k) Number	K121458	Unknown; this 510(k)	K072808
Regulation Name	Urological catheter and accessories	Same	Same
Regulation Number	21 CFR § 876.5130	Same	Same
Product Code	GBM	Same	Same
Classification	II	Same	Same
Prescription Device	Yes	Same	Same
Indications for Use	The product is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.	Same	Same
Function of device	The catheter is inserted into the urethra to reach the bladder allowing urine to drain into a collection bag.	Same as Reference Device.	The catheter is inserted into the urethra to reach the bladder allowing urine drainage.
Gender	Male	Same as Predicate	Female
Intermittent use and single use	Yes	Same	Same
Ready to use	Yes	Same	Same
Catheter composition	(b)(4)		
Hydrophilic coating			
Coating activating saline solution			
Packaging	Packaging consists of tube, cover and plug,	Same as Reference Device	Packaging consist of tube, closure and plus,

	which are made of <b>turquoise colored</b> polypropylene.		which are made of <b>light green</b> colored polypropylene.
Approximate lengths	Length catheter: 30 cm  Total length catheter, connector and handle: 36 cm  Coated length: 29 cm	Length catheter: 30 cm  Total length catheter and connector (male): 33.5 cm  Coated length: 29 cm	Length catheter: 7cm  Total length catheter and handle: 15.5 cm  Coated length: 5.5-7 cm
Approximate packaging size	Diameter 2.3 cm Length 21 cm	Diameter 1.6 cm Length 19 cm	Diameter 1.3 cm Length 9 cm
Volume of saline solution	Male 9 ml	3±1 ml	1.2±0.1 ml
Sterilization method	(b)(4)	(b)	(b)
Biocompatibility per ISO 10993	Complies	Same	Same
Low Friction (ASTM D 1894-11)	Yes	Same	Same
Compliance to flow rate according to ASTM F 623-99	Complies	Same	Same
Tensile strength according to test method EN 1618 and specification EN1617	Complies	Same	Same
Shelf life	2 years	Same (according to stability protocol)	Same
Available sizes	One size (FR 12/18)	Same as Predicate	6FR – 14FR

**Table 1** gives an overview of similarities and differences between SpeediCath Compact Male and the predicate device.

## 510(k) Summary

### SpeediCath Compact Male

(as required per 21 CFR § 807.92)

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The assigned 510(k) number is: \_\_\_\_\_

Submitter: Coloplast Corp  
1601 West River Road North  
Minneapolis, MN 55411

Contact Person: Brian E. Schmidt  
Regulatory Affairs Manager  
Coloplast Corp  
1601 West River Road  
Minneapolis, MN 55411  
  
Office: (612) 302-4987  
Fax: (612) 287-4138  
e-mail: usbes@coloplast.com

Date Prepared: November 3, 2014

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#### Device Name and Classification

Trade Name: **SpeediCath Compact Male**  
Common Name: Urinary Catheter for Intermittent Use  
Classification Name: Gastroenterology-Urology Devices  
Product Code: GBM

#### Legal Manufacturer

Coloplast A/S  
Holtedam 1  
DK-3050 Humlebaek Denmark

#### Device Description

The **SpeediCath Compact Male** is a sterile, single use, disposable (b)(4) catheter for males. The catheter is pre-lubricated with a (b)(4) (b)(4) To prepare the catheter for use, the cover is removed and the catheter is pulled out of the packaging thereby extending and locking it to its full length. The catheter is then ready to use allowing easy drainage.

## Substantial Equivalence Claim

The proposed **SpeediCath** Compact Male is substantially equivalent in form and function to Coloplast's **SpeediCath** Compact Set Male, which was cleared under 510(k) K121458 on October 1, 2012.

**SpeediCath** Compact Male and the predicate device are sterile, single use catheters for intermittent use with hydrophilic coatings.

Both **SpeediCath** Compact Male and the predicate device are ready to use catheters with identical hydrophilic coatings immersed in identical (b)(4). Furthermore, both **SpeediCath** Compact Male and the predicate device uses the same type of catheter design: telescope catheter.

The main difference between **SpeediCath** Compact Male and the predicate device is the packaging configuration and visual appearance. **SpeediCath** Compact Male does not have a pre-attached urine collection bag like the predicate device. The **SpeediCath** Compact Male packaging configuration has the same ready to use features as the predicate, and is packaged in a green discrete container instead of a turquoise colored. Equivalent to the predicate device, **SpeediCath** Compact Male is short in storage and is extended to its full length due to the telescopic extension of the catheter.

## Indications for Use

**SpeediCath** Compact Male is indicated for use by patients with urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

## Summary of Testing

**SpeediCath** Compact Male has been tested and complies with relevant sections of ASTM F 623-99, ASTM D1894-11, EN 1616, EN 1617 and EN 1618.

Performance Testing included:

- Flow Rate
- Coefficient of Friction
- Tensile Strength

**SpeediCath** Compact Male has been tested and complies with relevant sections of ISO 10993, Biological Evaluation of Medical Devices.

Biocompatibility Testing included:

- (b)(4)
- 
- 
-

## Description

**SpeediCath Compact Male** (see **Figure 1**) is intended for intermittent catheterization of the urinary bladder. The catheter is inserted into the urethra to reach the bladder allowing urine drainage. The product is available in one size and is for male users only.



Top: Unopened

Bottom: Catheter pulled out of tube and ready to use

**Figure 1. SpeediCath Compact Male**

The **SpeediCath Compact Male** is a sterile, ready to use, single use, disposable catheter packed individually in a firm packaging.

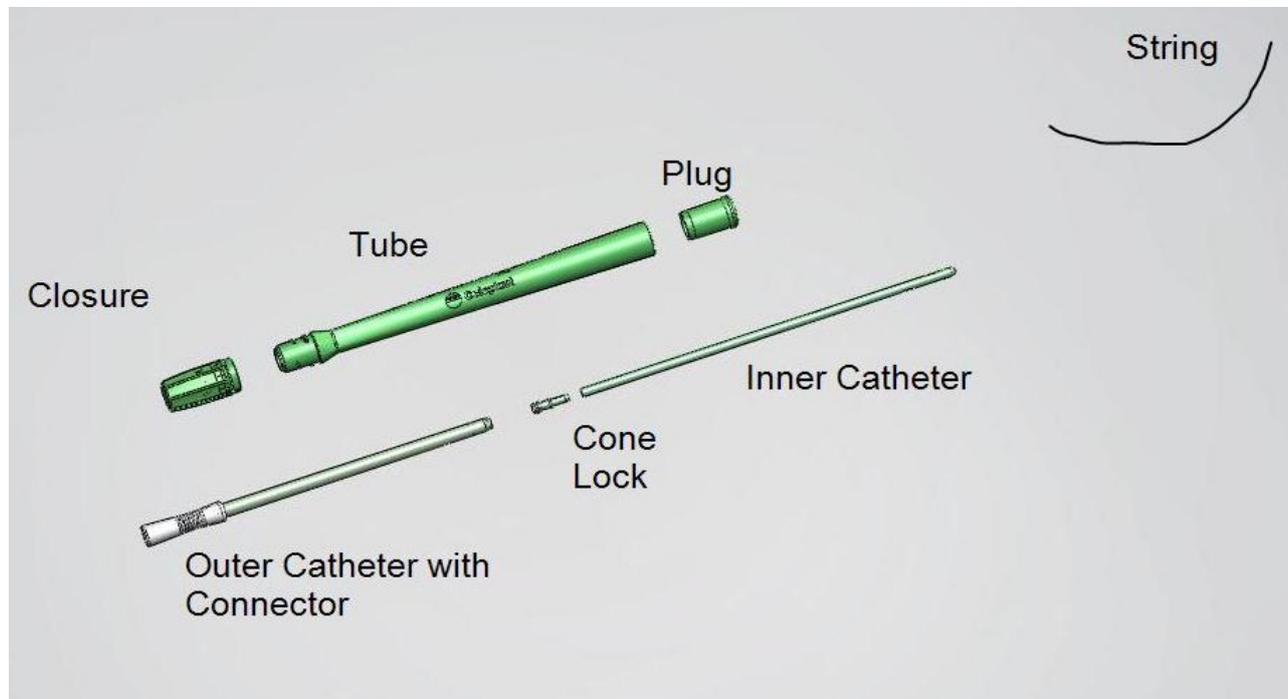
(b)(4)

(b)(4)

To use, the patient turns the closure and the tube in opposite directions breaking the seal. The closure is then removed. When pulling the connector out of the tube the catheter is extended and locked in its full length. W0hen pulling even further the string breaks and the fully extended catheter can be taken out of the tube and is now ready to insert into the bladder using the connector to insert the catheter into the urethra. An animated video is provided (in CD form, sent to the Document Mail center with the 510k hardcopy) to demonstrate how the product is opened and prepared for use. When in use the urine flows through the catheter and connector and into the toilet. After use, the product can be resealed and discarded.

## Component Descriptions

SpeediCath Compact Male is made up of the components described in the following:



**Figure 2.** SpeediCath Compact Male Components (coating and solution not illustrated).

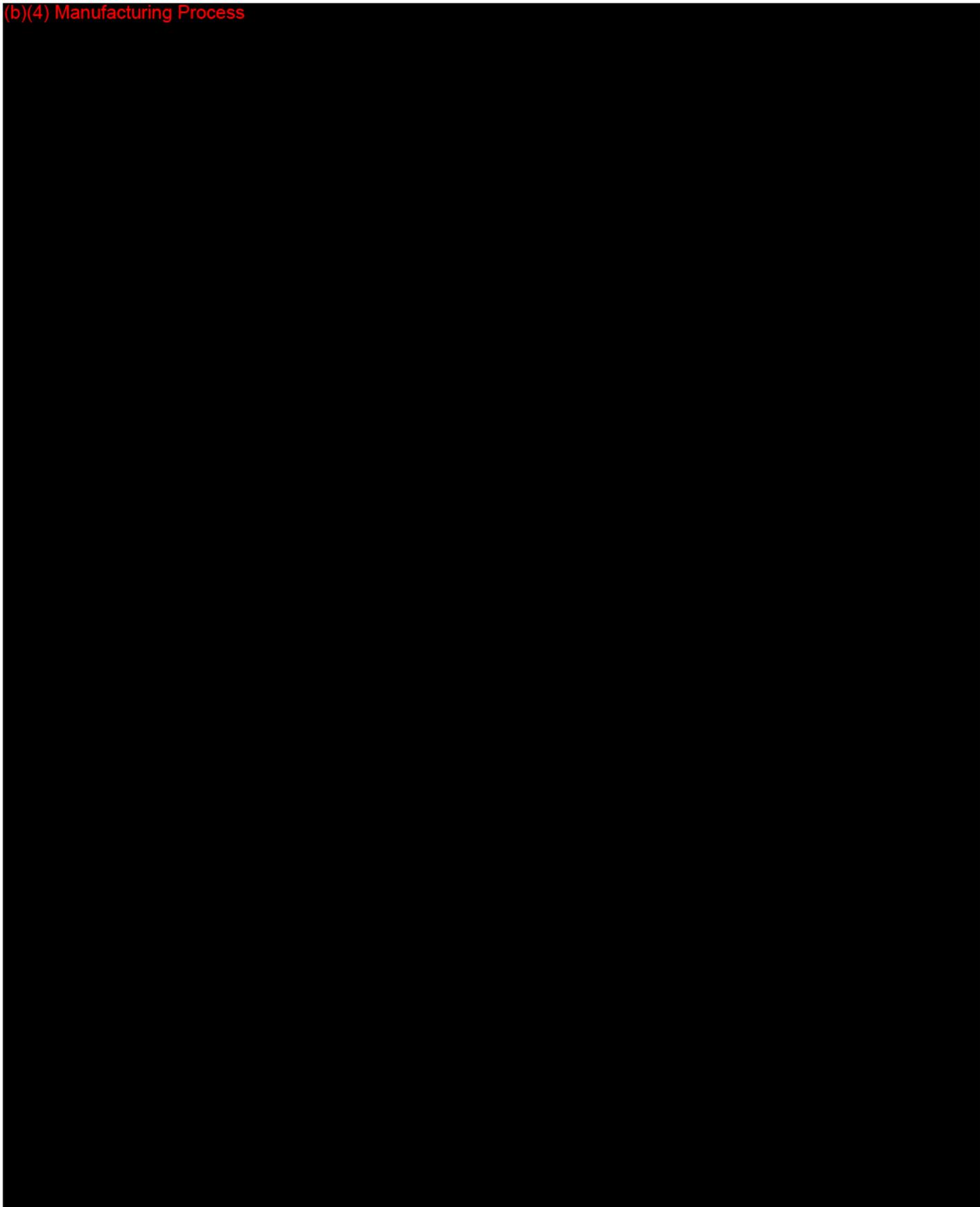
### Catheter

The catheter is composed of three parts: Inner Catheter, Outer Catheter and Cone Lock, see **Figure 2**.

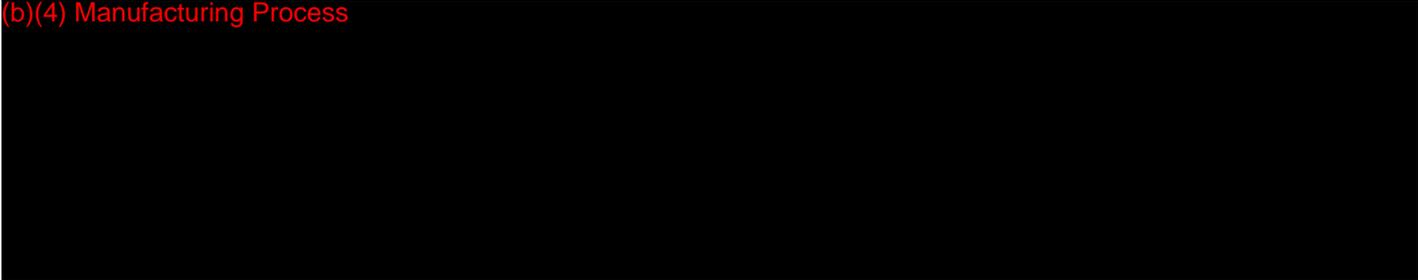
The inner and outer catheters make up the length of the catheter. Before use, the inner catheter is placed inside the outer catheter. When pulling the connector the two catheter parts are pulled to form the full catheter length – like a telescope. They are held together and locked by the cone lock when extended (see **Figure 3**). The materials used for Inner Catheter, Outer Catheter and Cone Lock for **SpeediCath** Compact Male are also used in the catheter components for the predicate device.

(b)(4)

(b)(4) Manufacturing Process



(b)(4) Manufacturing Process



## Engineering Drawings

**Table 2** gives overview of engineering drawings for **SpeediCath** Compact Male. For further details see **Appendix 1**.

Description	Engineering drawing number
(b)(4)	(b)(4) Manufacturing Process

*Table 2* Overview of engineering drawings

## Declarations of Conformity and Summary Reports

The **SpeediCath** Compact Male is in compliance with the standards listed in **Table 3**. Copies of FDA Form FDA-3654, Standards Data Report for 510(k)s for each of the voluntary standards listed below are provided in **Appendix 2**.

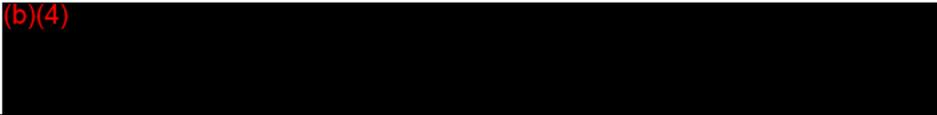
Number and Title of Voluntary Standard		Recognized Standard
Biological		
ISO 10993-1:2009/AC2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Yes
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Yes
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Yes
ISO 10993-12:2007	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	Yes
Risk Management		
ISO 14971:2007	Medical devices – Application of risk management to medical devices	Yes
Performance		
EN 1616:1997	Sterile Urethral Catheters for Single Use	No
EN 1617:1997	Sterile drainage catheters and accessory devices for single use	No
EN 1618:1997	Catheters other than intravascular catheters-Test methods for common properties	No
ASTM F 623-99:2006	Standard Performance Specification for Foley Catheter	Yes
ASTM D 1894-11:2011	Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting	No
Sterilization		
(b)(4)		Yes
		Yes

**Table 3** Voluntary Standards

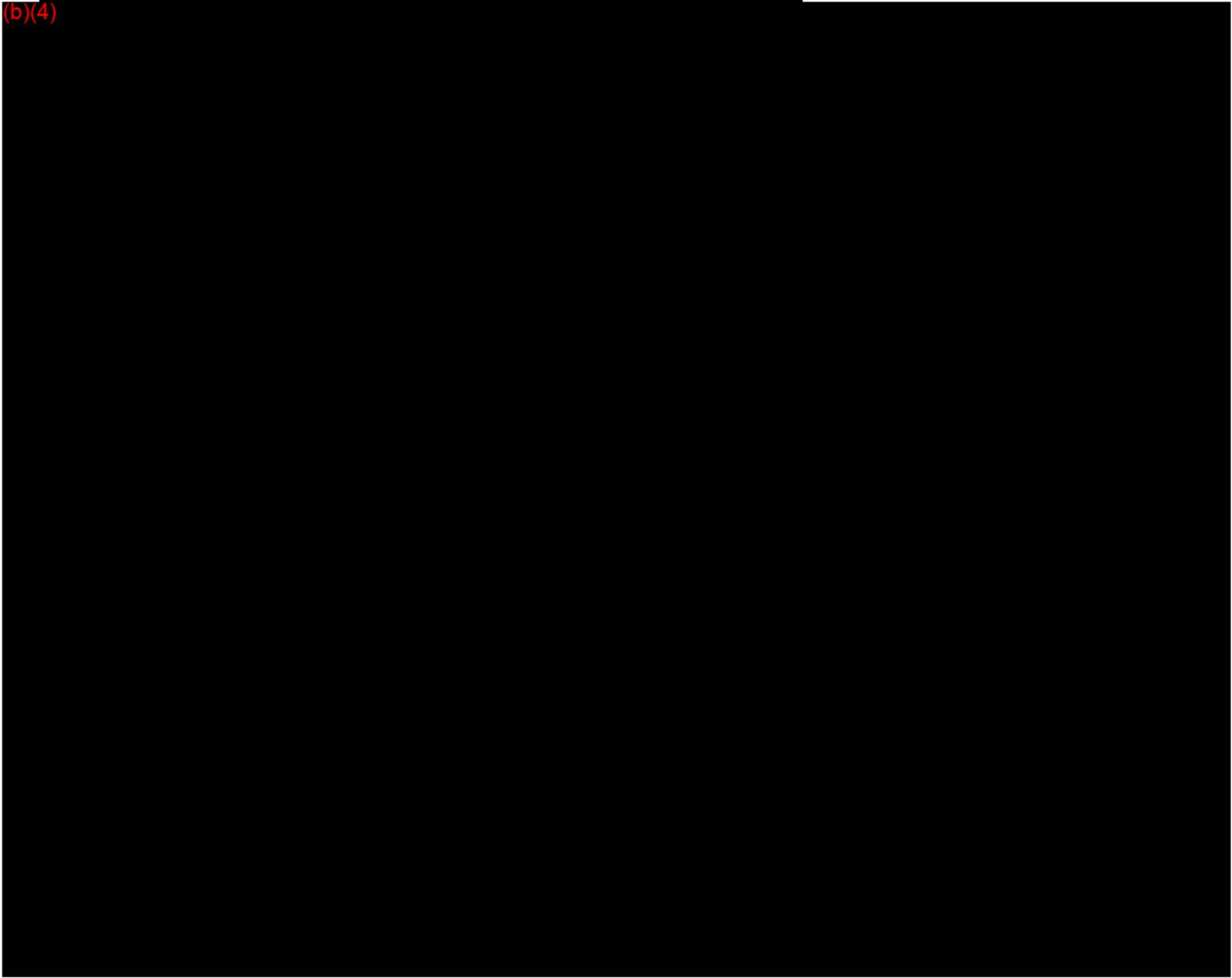
## Performance Data

**SpeediCath** Compact Male was CE-marked back in September 2010, and is currently sold in several markets including Europe. The **SpeediCath** Compact Male US variant is slightly different than the CE-marked variant in regards to the inner catheter. The inner catheter (for the US variant) differs from the CE marked variant per the following:

(b)(4)

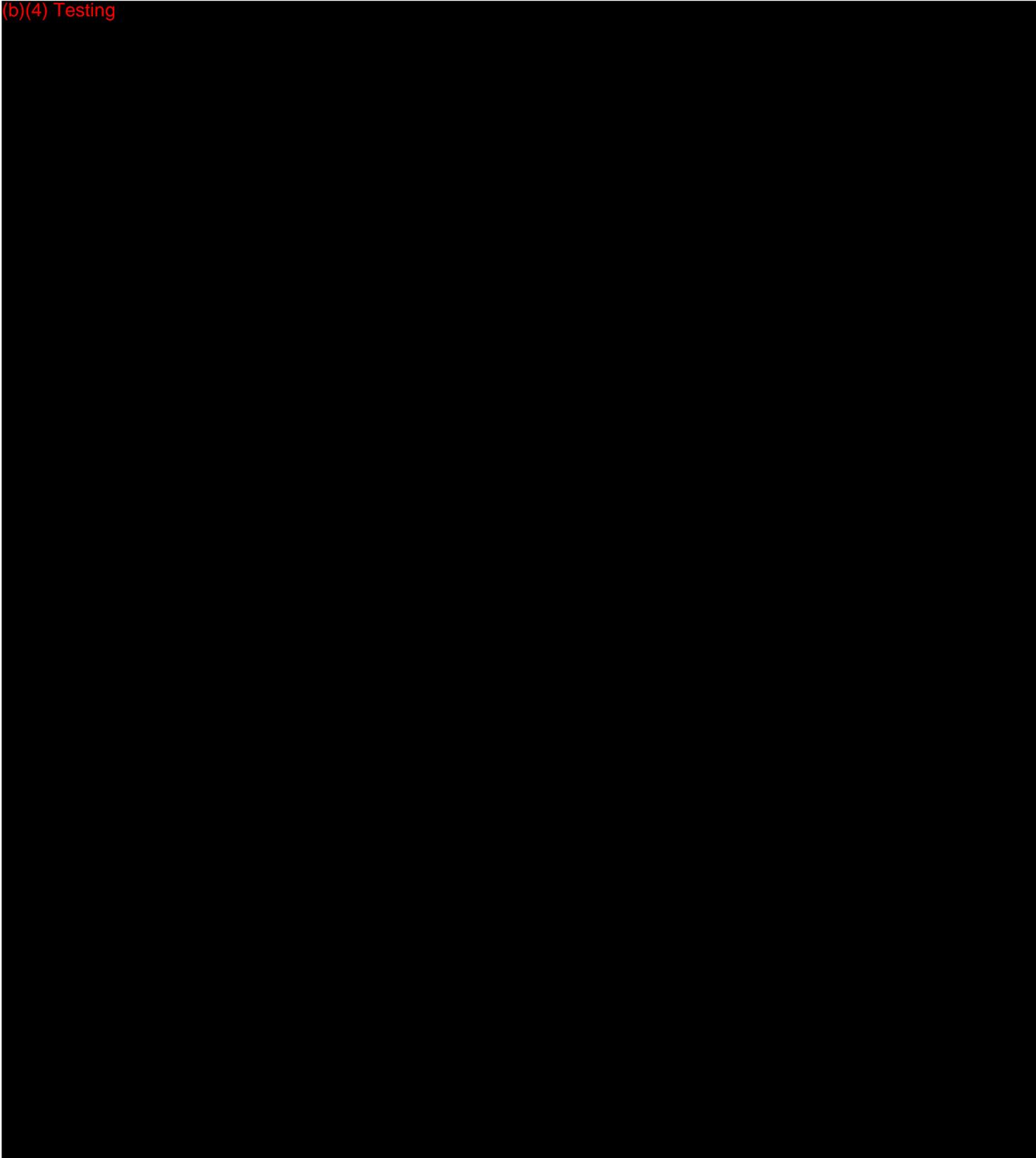
A large black rectangular redaction box covers the text following the first (b)(4) label.

(b)(4)

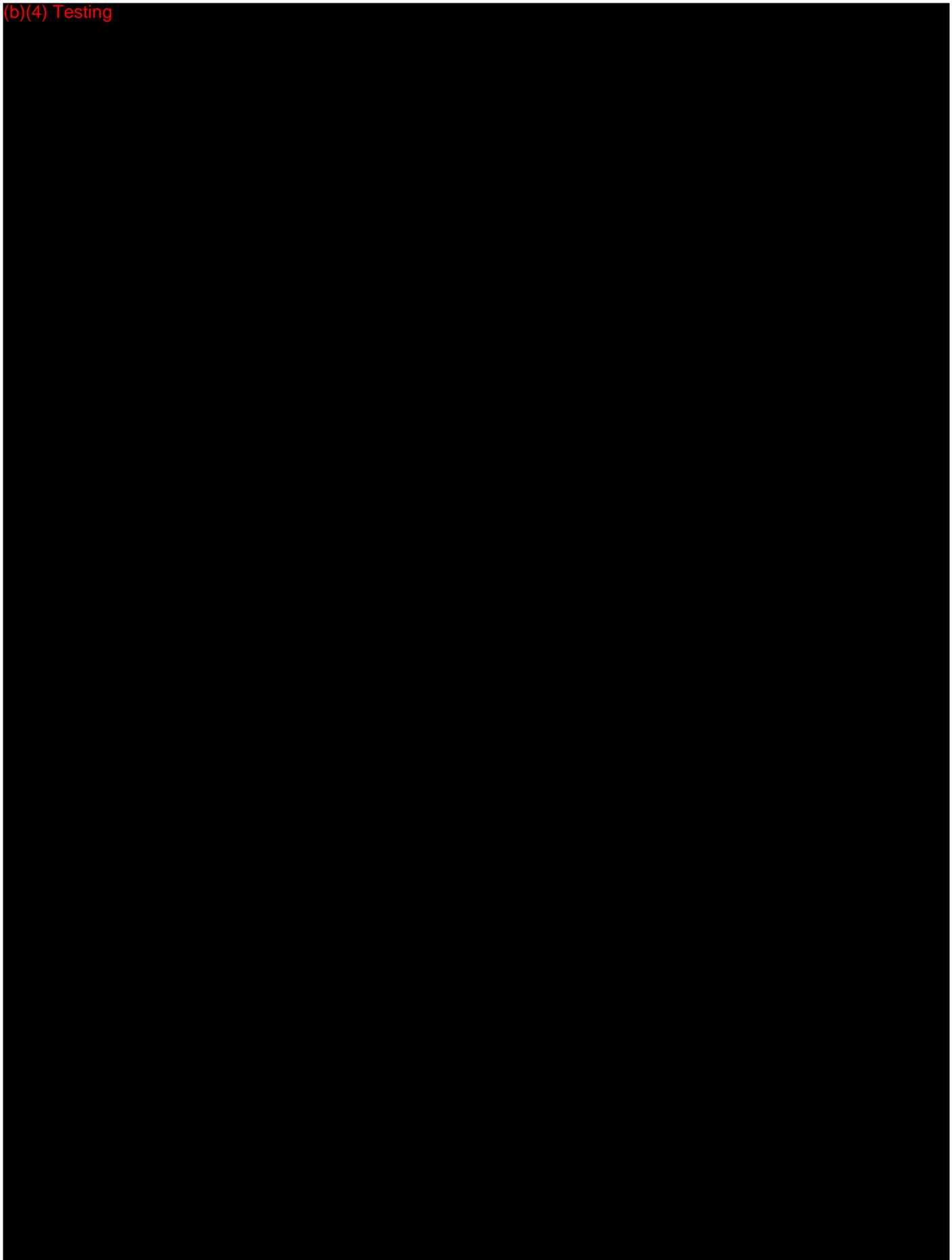
A very large black rectangular redaction box covers the majority of the page content, starting from the second (b)(4) label and extending to the bottom of the page.

See Results **Table 5.**

(b)(4) Testing



(b)(4) Testing



## **Shelf life**

**SpeediCath** Compact Male has a shelf life of 12 months based on accelerated data (3 month storage at 25°C/60%RH, 30°C/65%RH and 40°C/75%RH), where all properties are within the specified limits, see Stability Report **Appendix 4**.

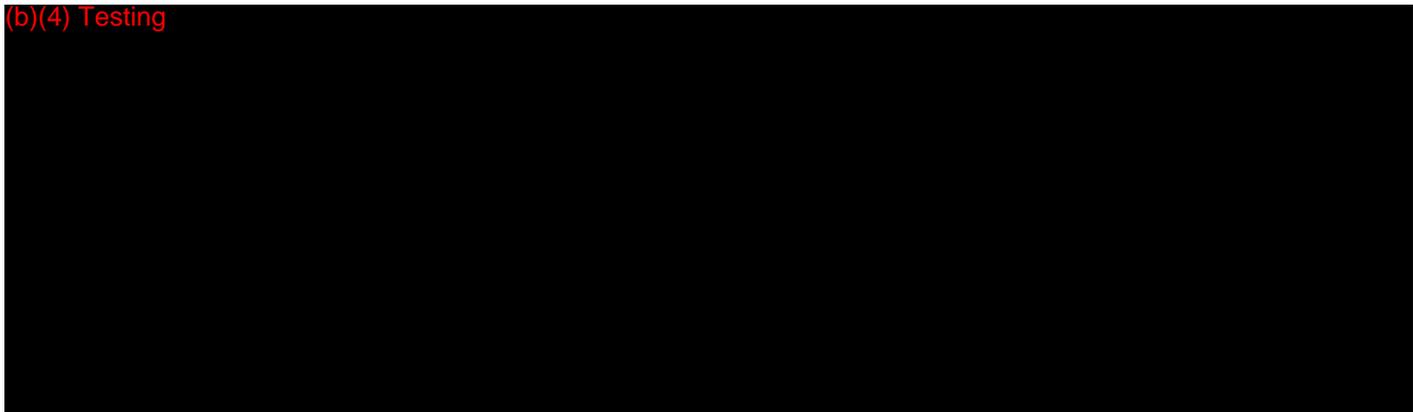
The shelf life for **SpeediCath** Compact Male including the raw inner catheter will be prolonged to two years as stability data becomes available and is acceptable, see Stability Protocol **Appendix 4**.

## **Biocompatibility**

Per ISO 10993-1, **SpeediCath** Compact Male is categorized as a surface device. The catheter part of the product is in direct contact with the mucosal membrane of the urethra. Although the product is for intermittent use (approximately 7 catheters per day with the average characterization time of 5 minutes), the duration of contact is classified as prolonged due to cumulative use.

The materials in the catheter component of **SpeediCath** Compact Male is essentially identical to the predicate device, except for the following differences:

(b)(4) Testing

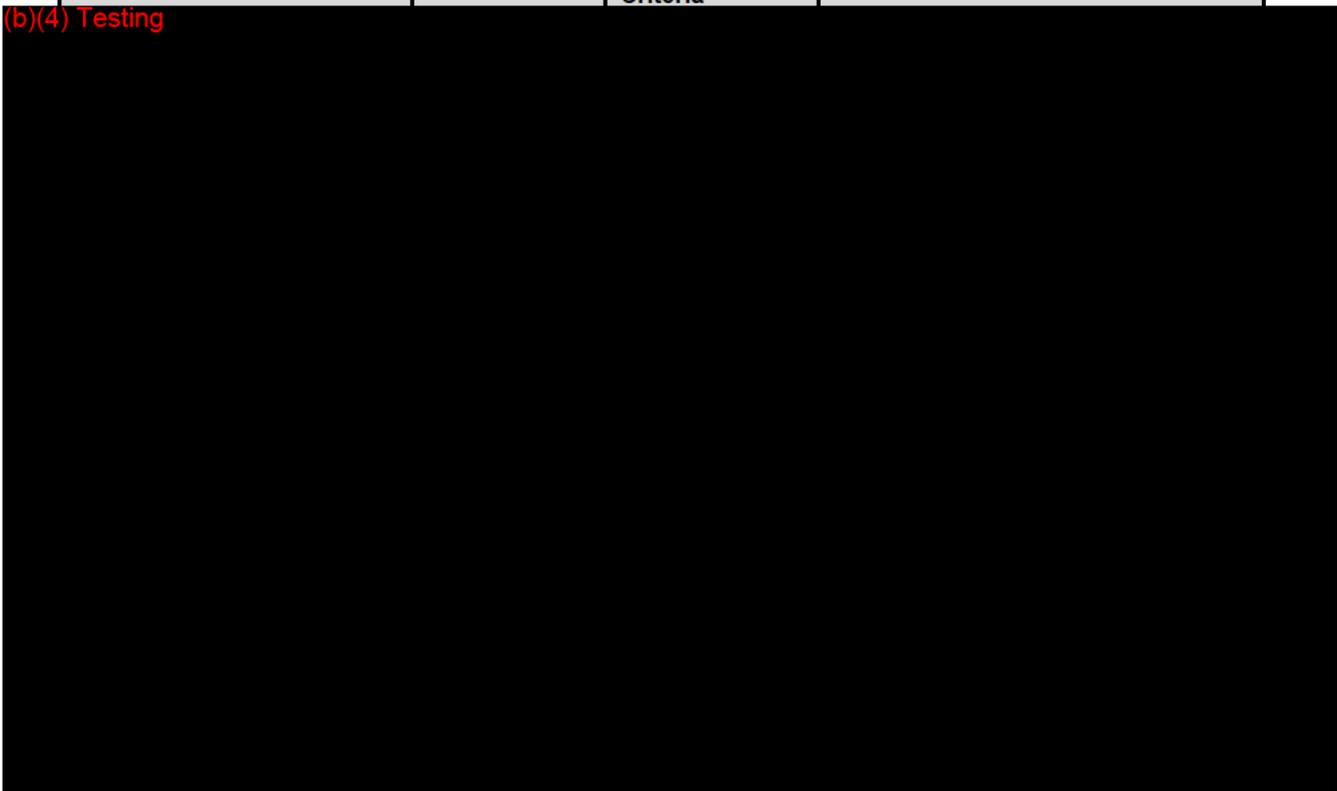


In conclusion, no new substances are found in the **SpeediCath** Compact Male catheter compared to the predicate device.

To confirm the biocompatibility of the **SpeediCath** Compact Male catheter, the biological tests as outlined in **Table 8** were conducted on the device.

Test	Report No	Acceptance Criteria	Results / Conclusion
------	-----------	---------------------	----------------------

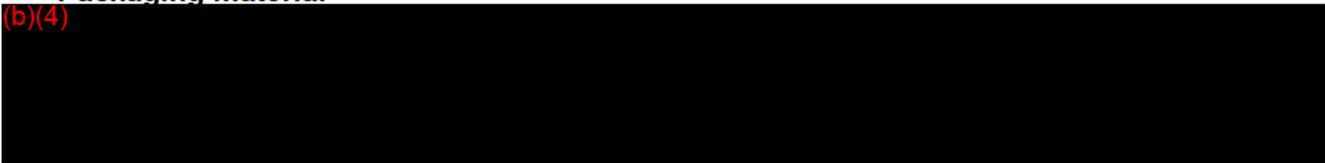
(b)(4) Testing



Based on the results of the biological tests for (b)(4) Testing it is concluded that **SpeediCath** Compact Male does not pose a risk of cytotoxicity, irritation or sensitization.

**Packaging material**

(b)(4)





**Figure 6.** Picture of the primary packaging material for: *Left:* Predicate device (**SpeediCath Compact Set**). *Middle:* Subject for submission (**SpeediCath Compact Male**). *Right:* Reference device (**SpeediCath Compact Female**)

The predicate device, the reference device and **SpeediCath Compact Male** use (b)(4) (b)(4). The **SpeediCath Compact Male** packaging (b)(4)

Overall, the most significant and visible difference between the packaging materials is (b)(4)

#### (b)(4) Manufacturing Process

Information about the pigments used in the unique masterbatches for **SpeediCath Compact Male** are outlined in **Table 9, 10** and **11**.

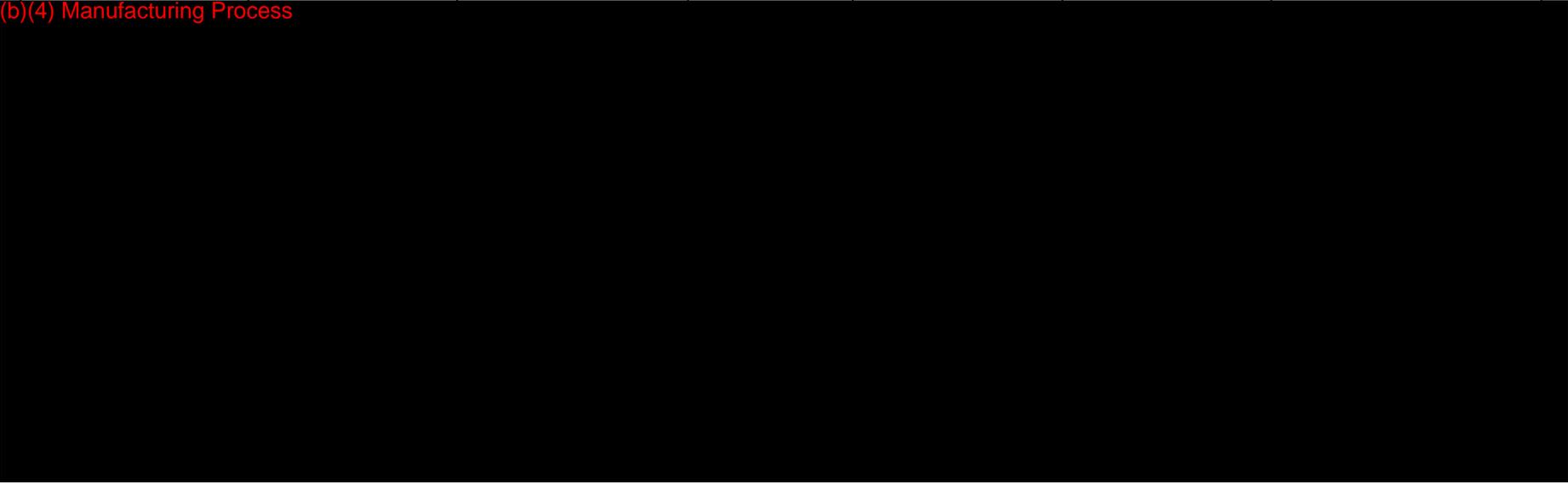
Master batch	Device component	Chemical name	CAS No.	Amount per device	Material Safety Data Sheet	Compliance to 21 CFR
--------------	------------------	---------------	---------	-------------------	----------------------------	----------------------

(b)(4) Manufacturing Process



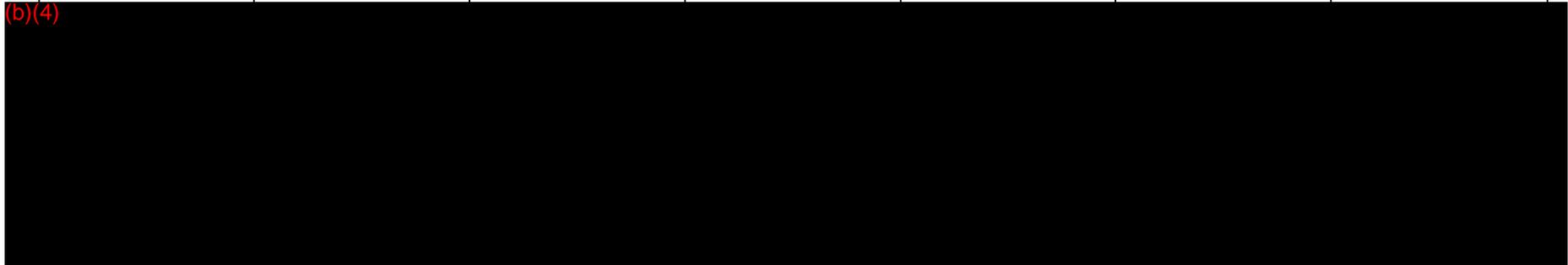
Master batch	Device component	Chemical name	CAS No.	Amount per device	Material Safety Data Sheet	Compliance to 21 CFR
--------------	------------------	---------------	---------	-------------------	----------------------------	----------------------

(b)(4) Manufacturing Process



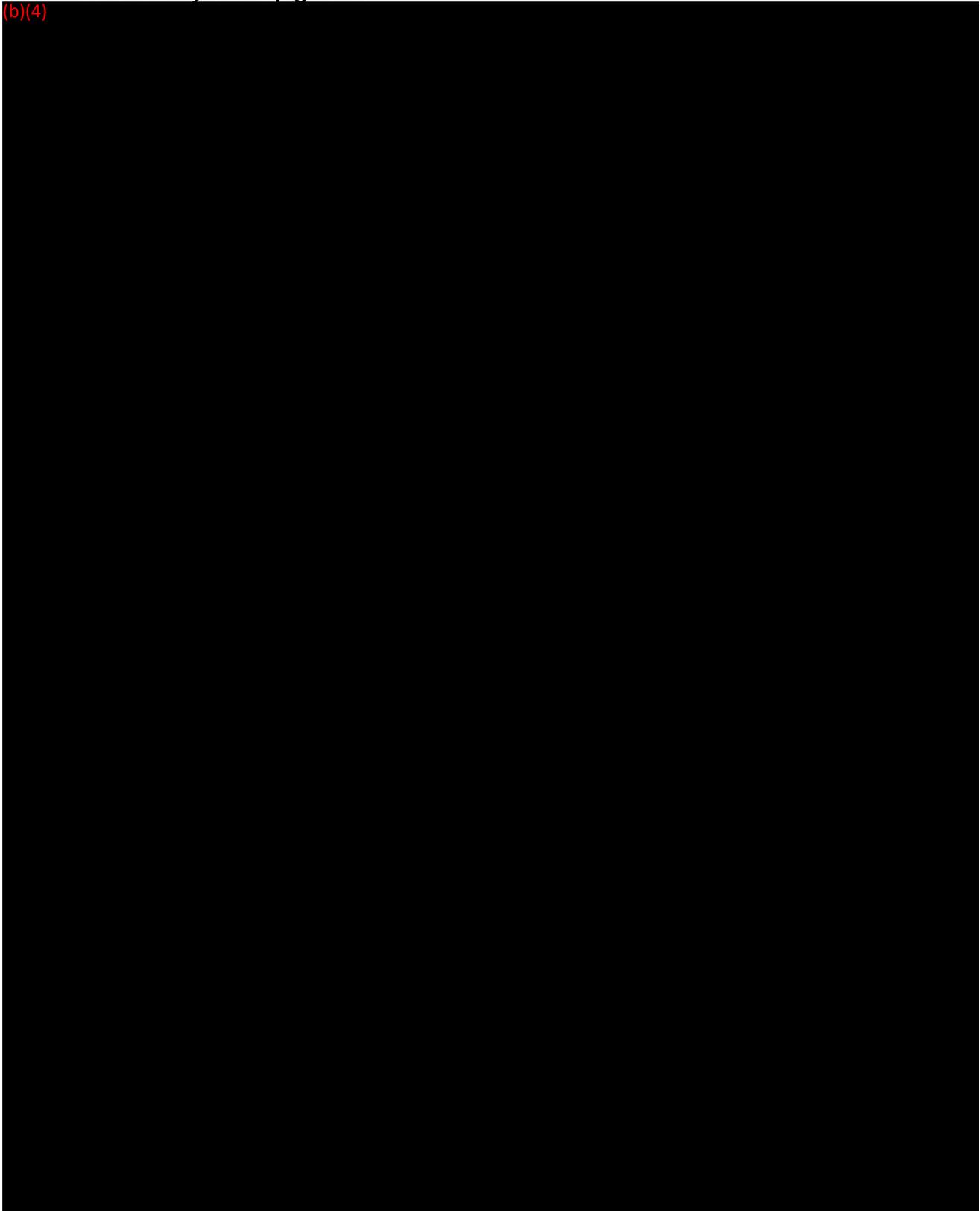
Master batch	Device component	Chemical name	CAS No.	Amount per device	Material Safety Data Sheet	Compliance to 21 CFR
--------------	------------------	---------------	---------	-------------------	----------------------------	----------------------

(b)(4)

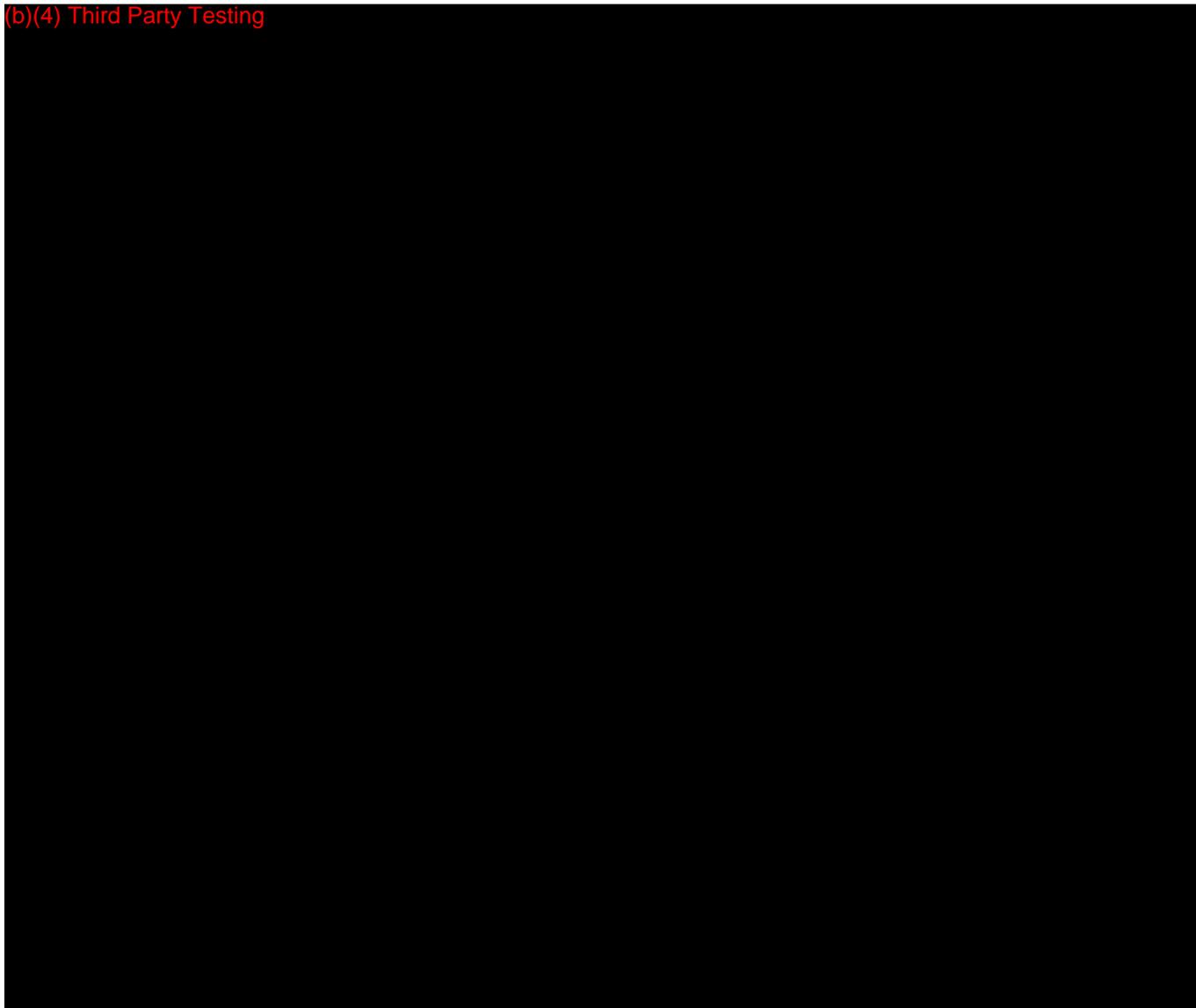


**Bioavailability of the pigments**

(b)(4)



(b)(4) Third Party Testing



**a** [Redacted]  
**b** [Redacted]

## Sterilization

**SpeediCath** Compact Male is sterilized by (b)(4) Third Party Information .

The product is sterilized to ensure a minimum dose of (b)(4)

(b)(4)

The sterilization process for **SpeediCath** Compact Male is the same sterilization method used for **SpeediCath** Compact Set Male.

### **Class III Certification**

Since this 510(k) does not pertain to a Class III device, the referenced Certification is not applicable to this application.

## **Financial Disclosure Statement**

This section does not apply, as there is no information from clinical studies presented within this premarket notification; therefore, financial disclosures are not required.















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**STANDARDS DATA REPORT FOR 510(k)s**  
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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 <sup>1</sup>

ISO 14971: 2007 Medical devices - Application of risk management to medical devices

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #5-40

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> 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) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....       
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Were there any exclusions from the standard? .....       
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

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DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM D 1894-11 Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheetting

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

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 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

Recognition Number 9-44: ASTM F 623 -99 (Reapproved 2006), Standard Performance Specification for Foley Catheter.

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 9-44

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
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If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: Guidance for Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters.

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

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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SUMMARY REPORT TABLE**

STANDARD TITLE

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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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DESCRIPTION

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DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

EN 1616: 1997 Sterile Urethral Catheters for Single Use

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes     No

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes     No

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....  Yes     No  
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? .....  Yes     No

Does this standard include acceptance criteria? .....  Yes     No  
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....  Yes     No  
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....  Yes     No  
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....  Yes     No

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....  Yes     No  
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....  Yes     No  
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....  Yes     No  
If yes, was the guidance document followed in preparation of this 510k? .....  Yes     No

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

EN 1617: 1997 Sterile Drainage Catheters and Accessory Devices for Single Use

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes     No

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes     No

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....  Yes     No  
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? .....  Yes     No

Does this standard include acceptance criteria? .....  Yes     No  
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....  Yes     No  
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....  Yes     No  
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Were deviations or adaptations made beyond what is specified in the FDA SIS?.....  Yes     No  
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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

EN 1618: 1997 Catheters other than intravascular catheters-Test methods for common properties

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes     No

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes     No

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Title of guidance: \_\_\_\_\_

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #2-156

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> 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?.....       
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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 <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of

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

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #2-153

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
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Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #2-173

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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 (To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-12:2007 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials.

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #2-135

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
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Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11137-1:2006/(R) 2010: Sterilization of health care products - Radiation - Part 1: Requirements for development, validation

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #14-297

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

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Title of guidance: \_\_\_\_\_

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

(b)(4)

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #14-225

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

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## Laboratory report

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(b)(4) Testing

## 2 Purpose of the test

(b)(4) Testing

## 3 Test information

(b)(4) Testing

## 4 Product information

(b)(4) Testing

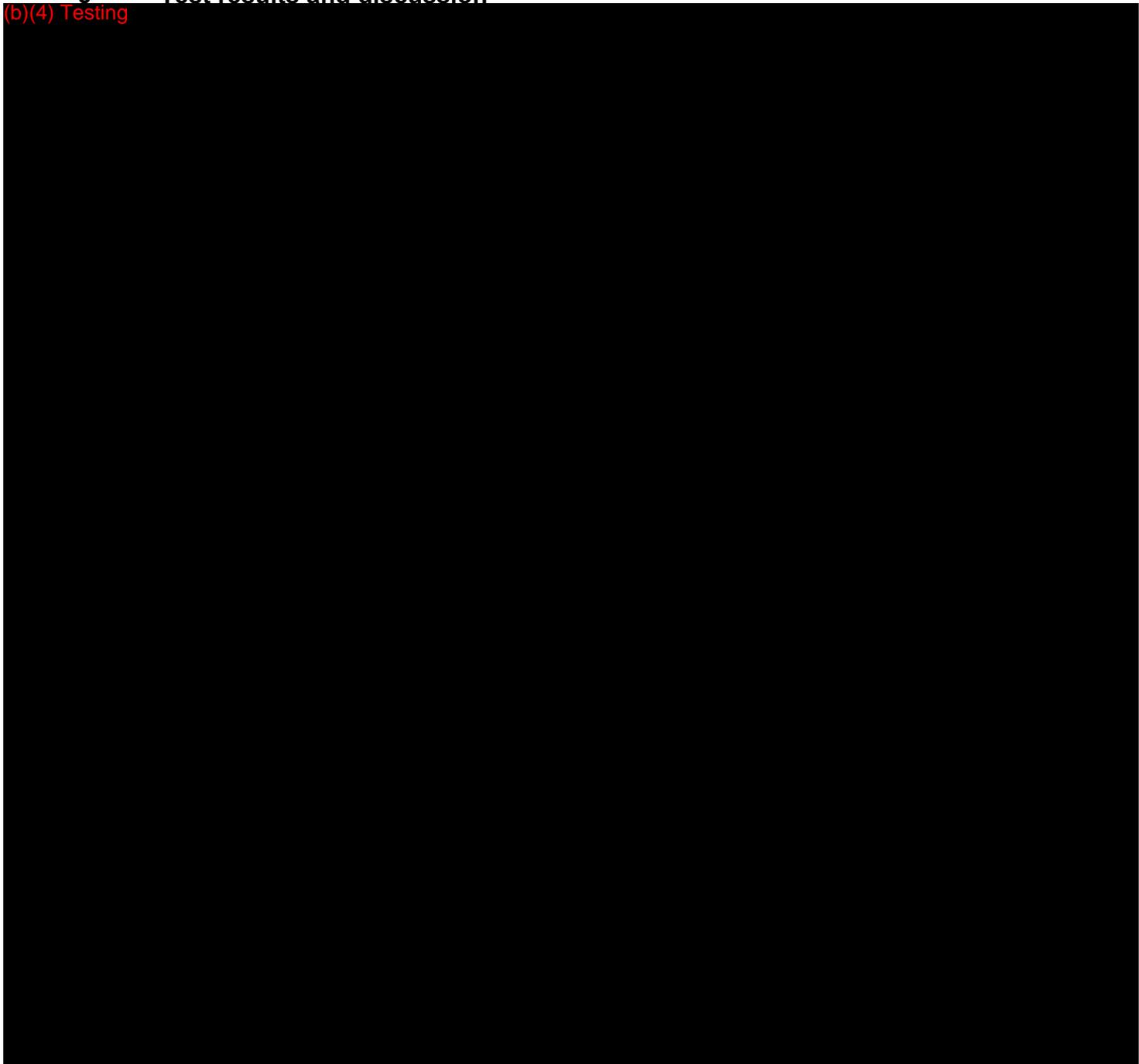
## 5 Test method and equipment

(b)(4) Testing

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## 6 Test results and discussion

(b)(4) Testing



## 7 Conclusion

(b)(4) Testing



## 8 Filing of raw data

Raw data are filed in lab request (b)(4)

1 ti

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## 9 Change log

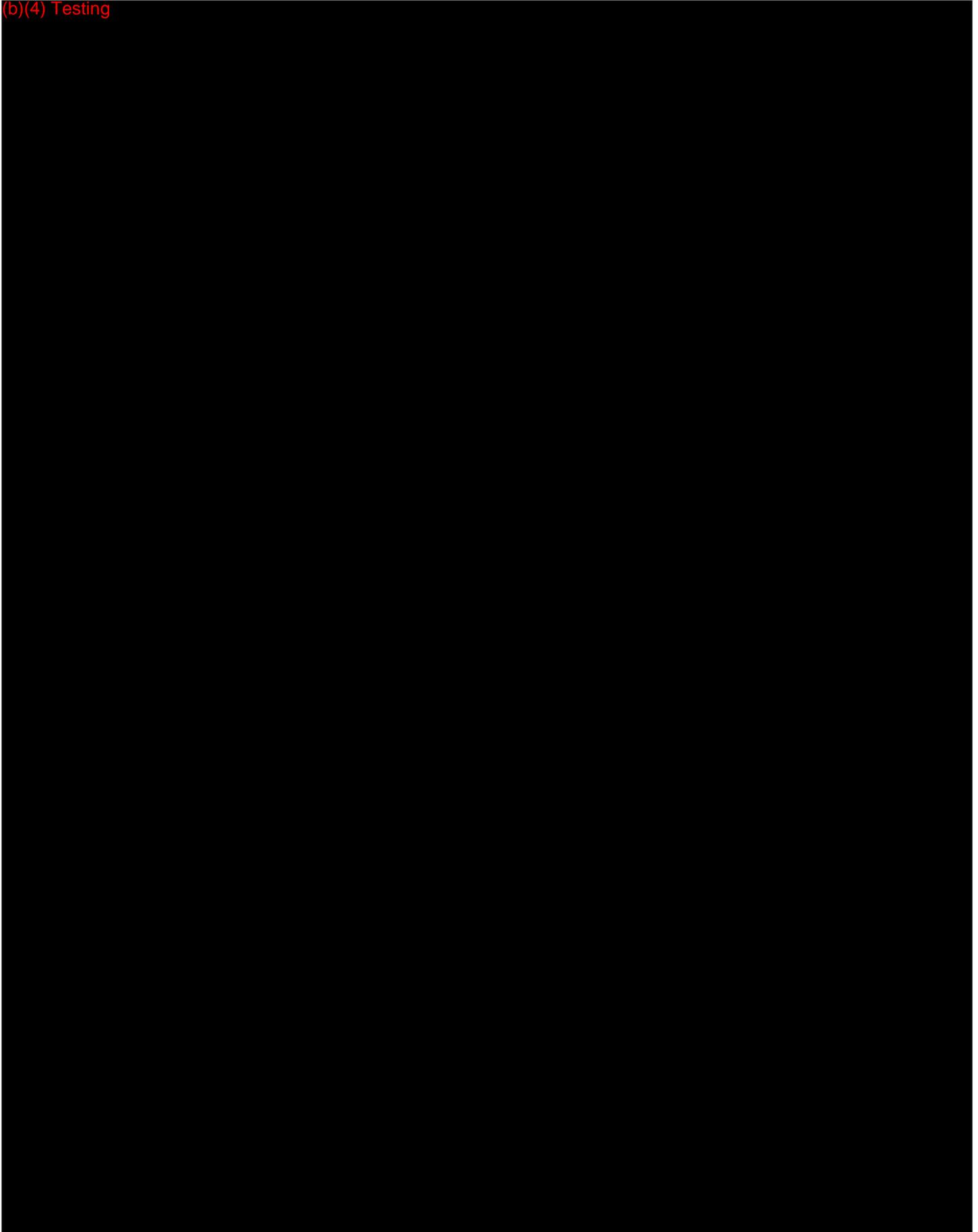
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1	(b)	Document established based on template version (b)

## 10 Appendix

(b)(4) Testing

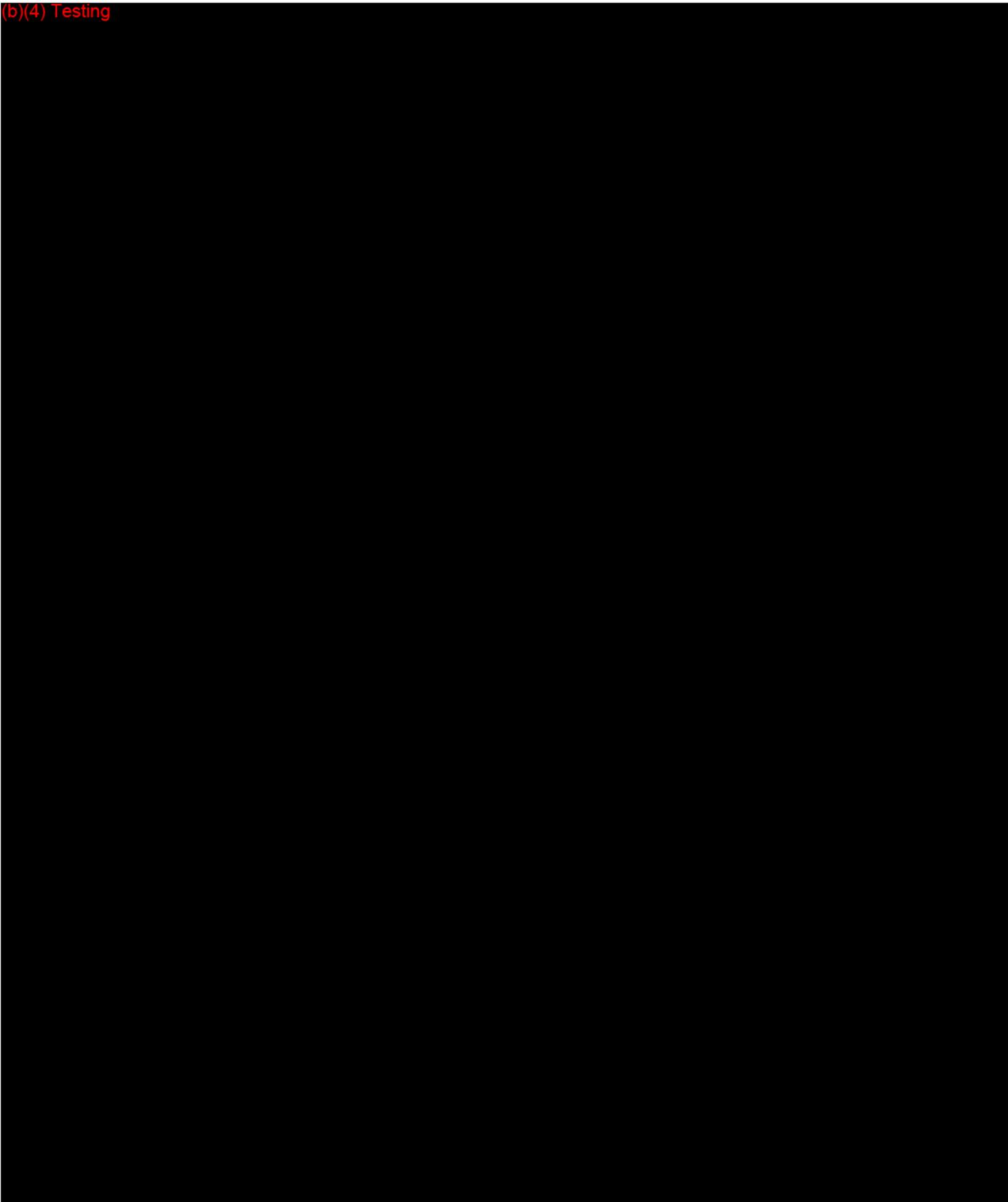


(b)(4) Testing

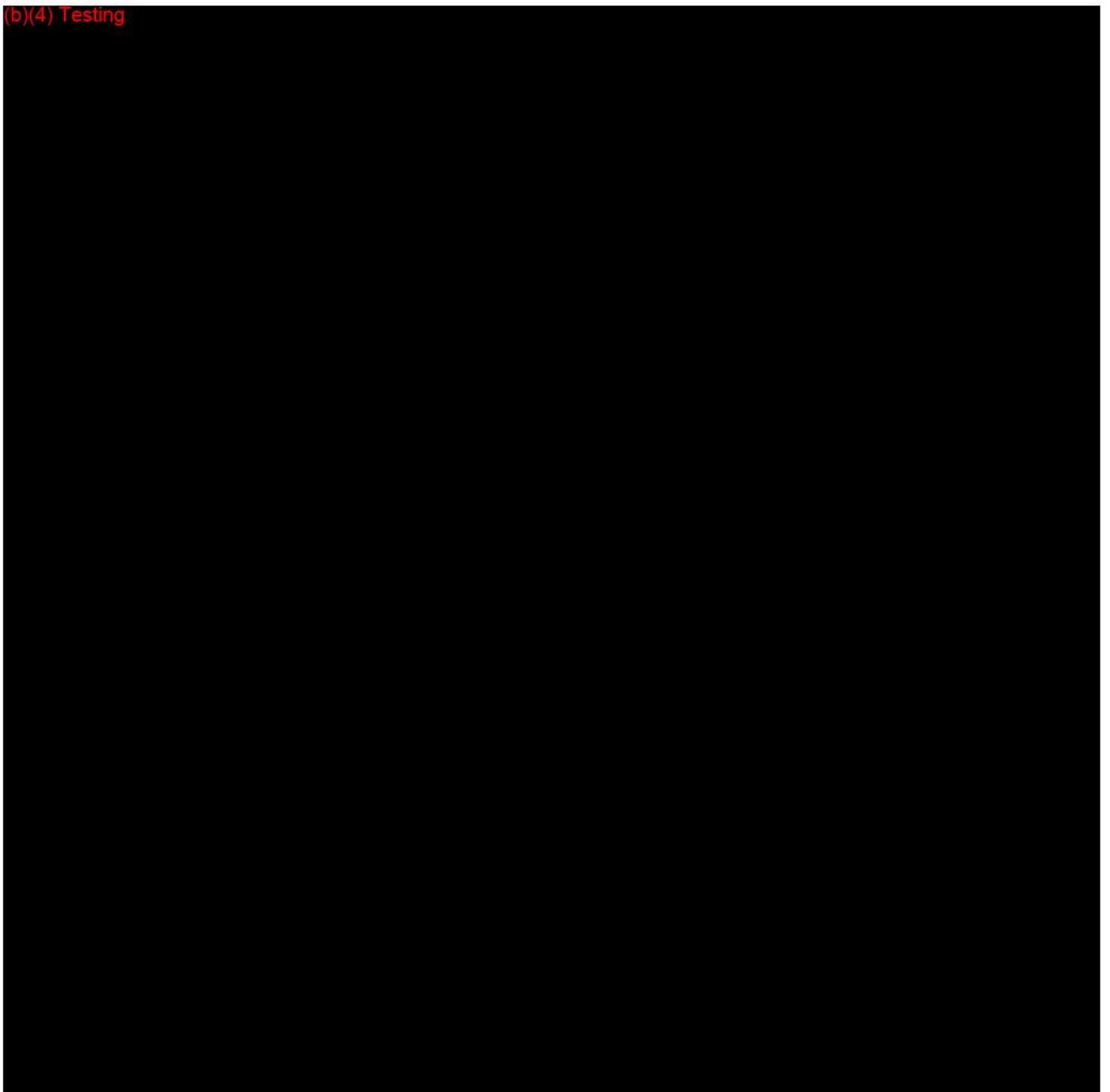


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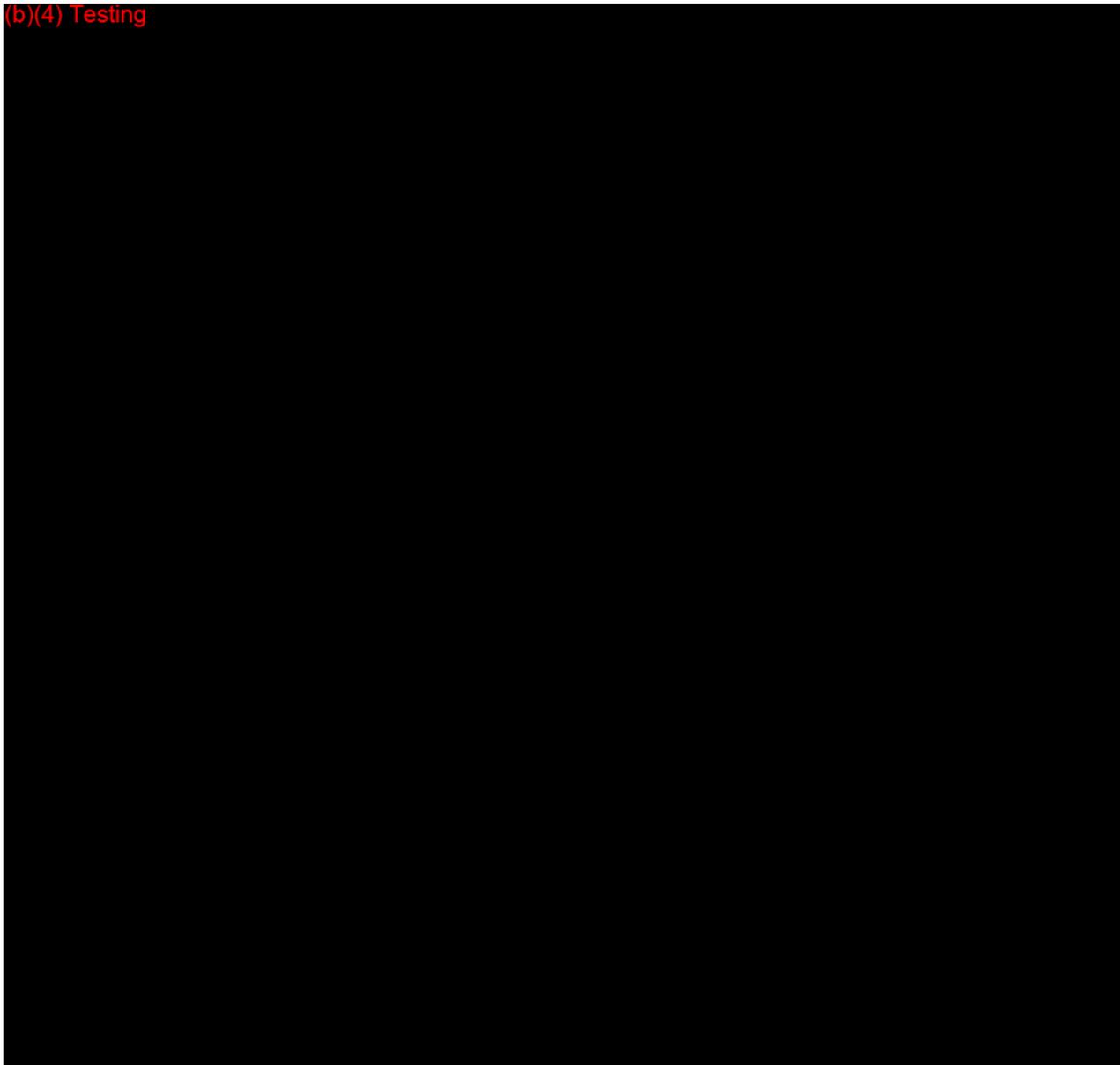
(b)(4) Testing



(b)(4) Testing



(b)(4) Testing

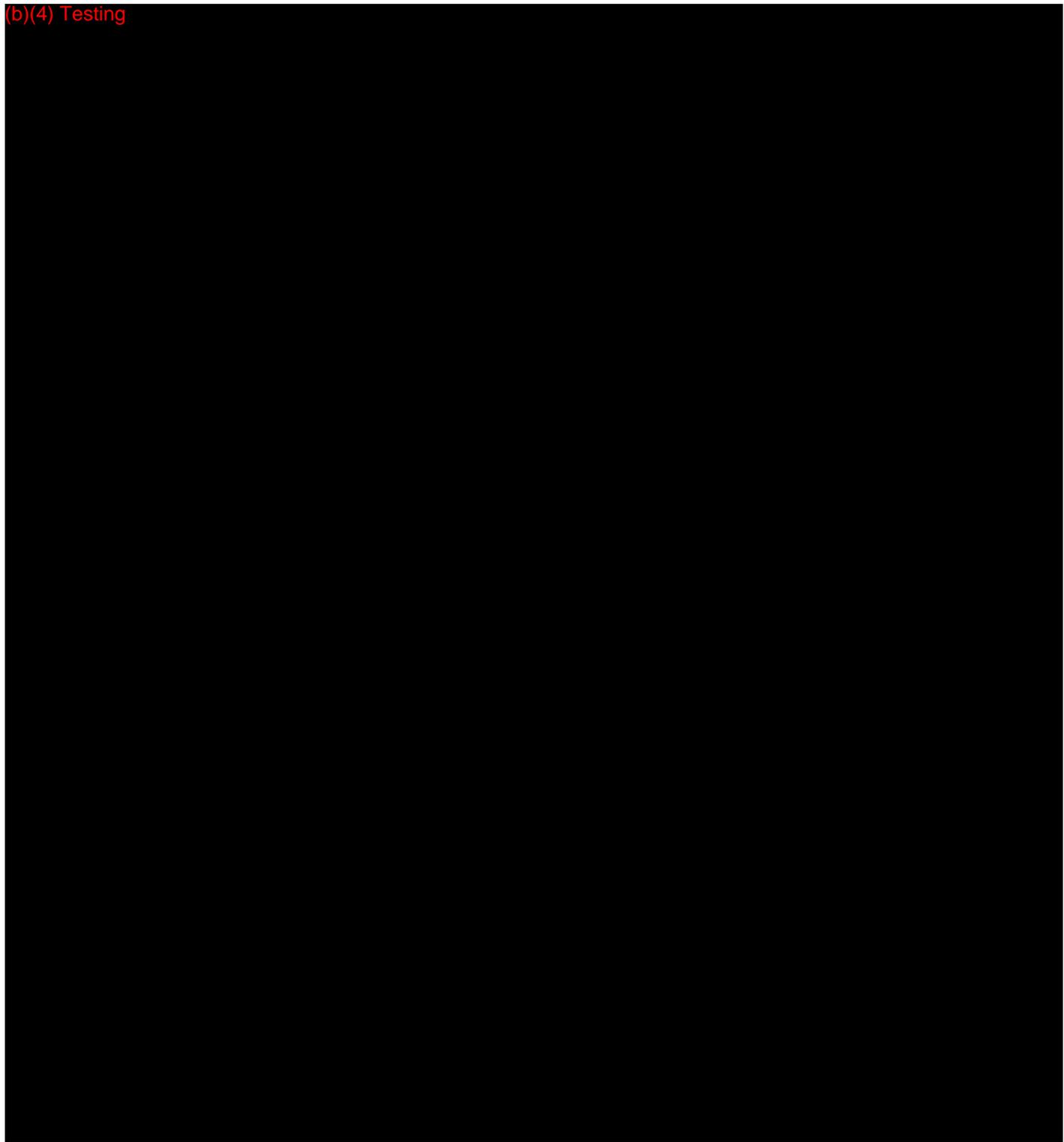


## SIGNATURE PAGE

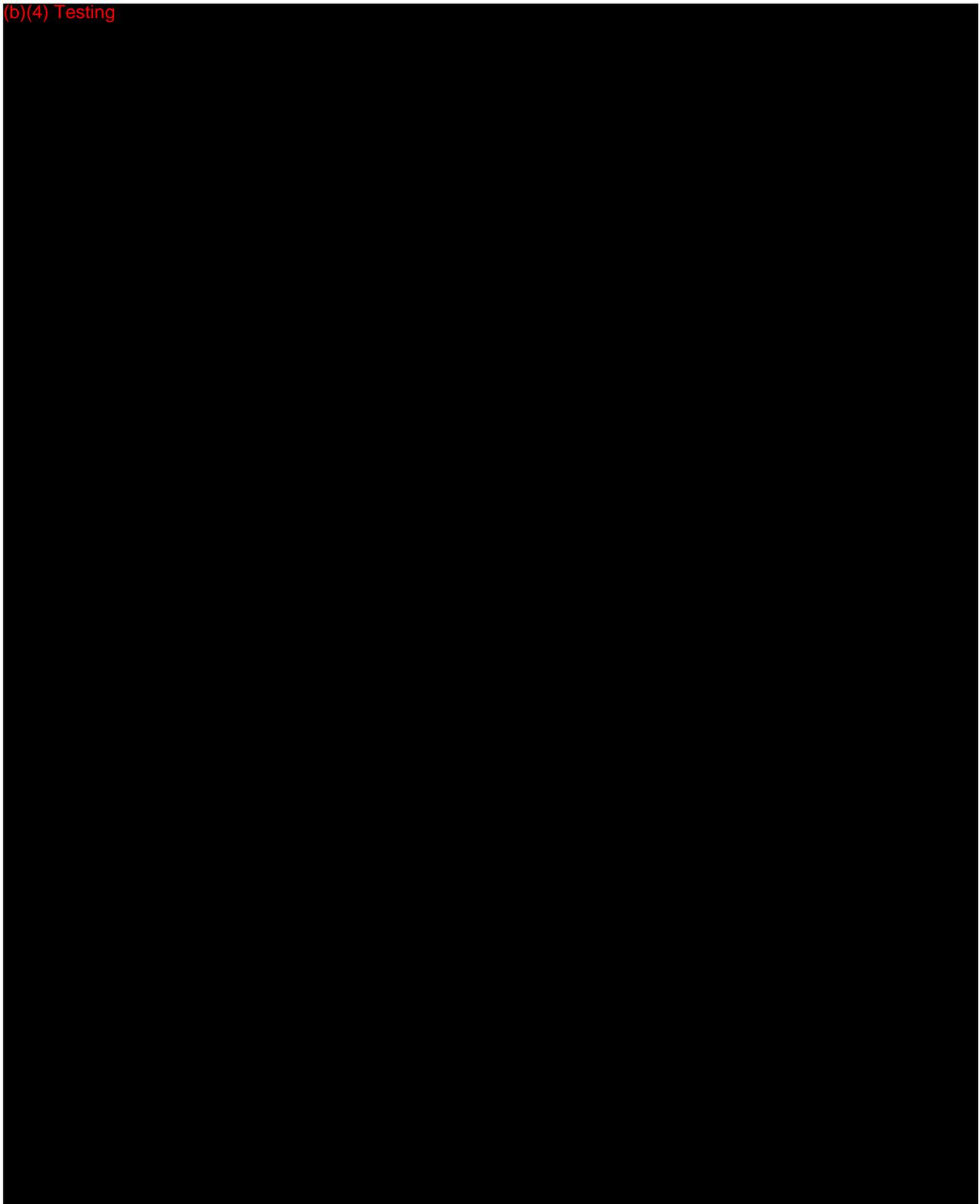
Date (GMT)	Signed by
2014/09/03 08:53:13	(b)(6)
Justification	Sr. Product support specialist
Justification	

This is an electronically signed document

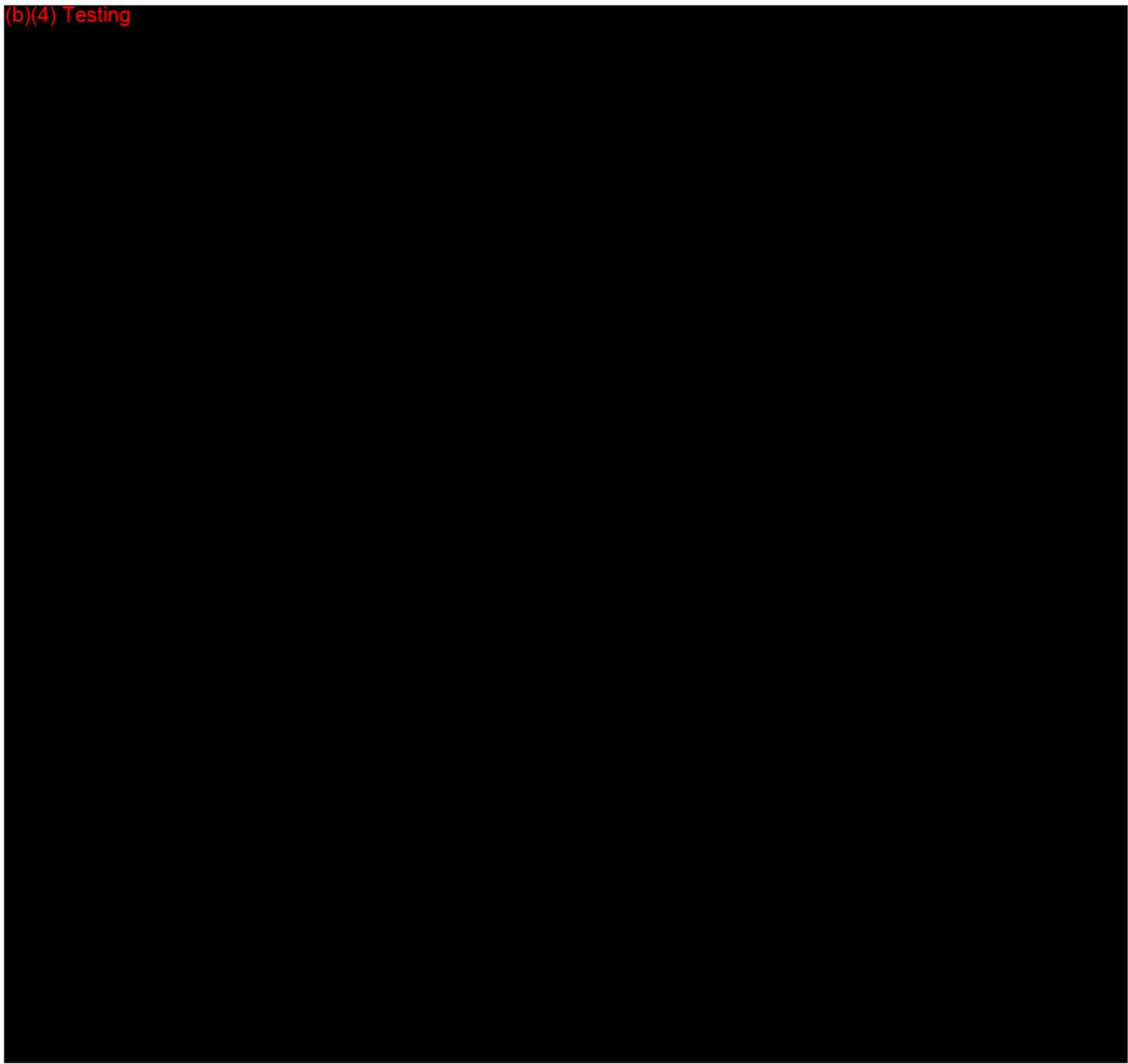
(b)(4) Testing



(b)(4) Testing



(b)(4) Testing



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**6 Change log**

Version No.	Init.	Short description of and reason for change
1	(b)(6)	Document established based on template version (b)

## SIGNATURE PAGE

Date (GMT)	Signed by
2014/09/10 07:18:29	(b)(6)
Justification	Sr. Product support specialist
2014/09/10 07:42:12	(b)(6)
Justification	Regulatory Affairs Manager
Justification	

This is an electronically signed document

# Production Process and Traceability

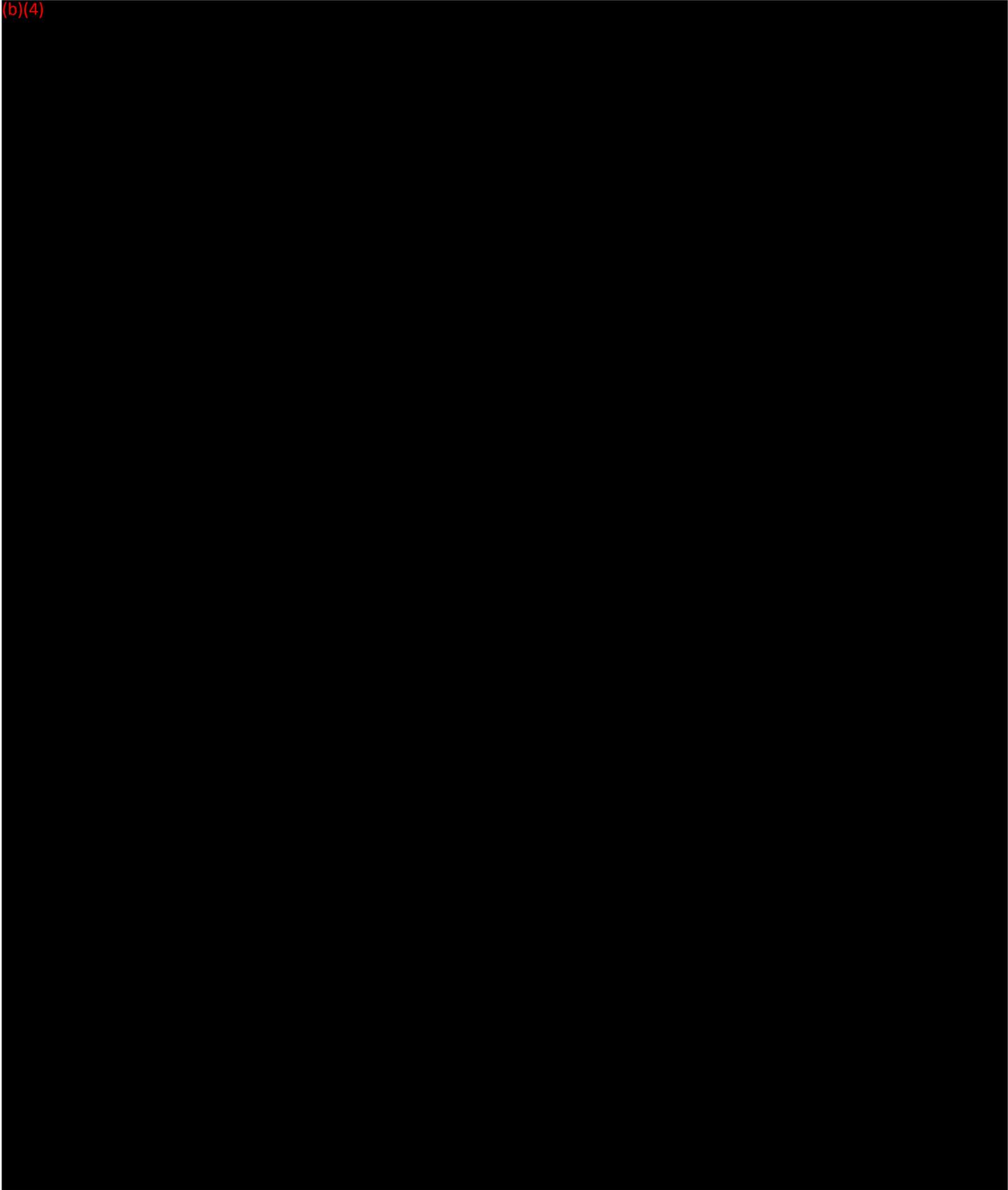
for SpeediCath Compact Male (SCCM) for US

This document covers the following productions:	
Production identification:	Production period:
(b)(4)	

1	Purpose	3
2	Production Process Description	4
3	Packaging	6
4	Sterilisation	7
5	Material Description – Traceability	7
6	Change Log	9
7	Appendix 1 – Materials used for assembly	9
8	Appendix 2 – Process parameters: Coating	9
9	Appendix 3– Sterilization document	9

## 1 Purpose

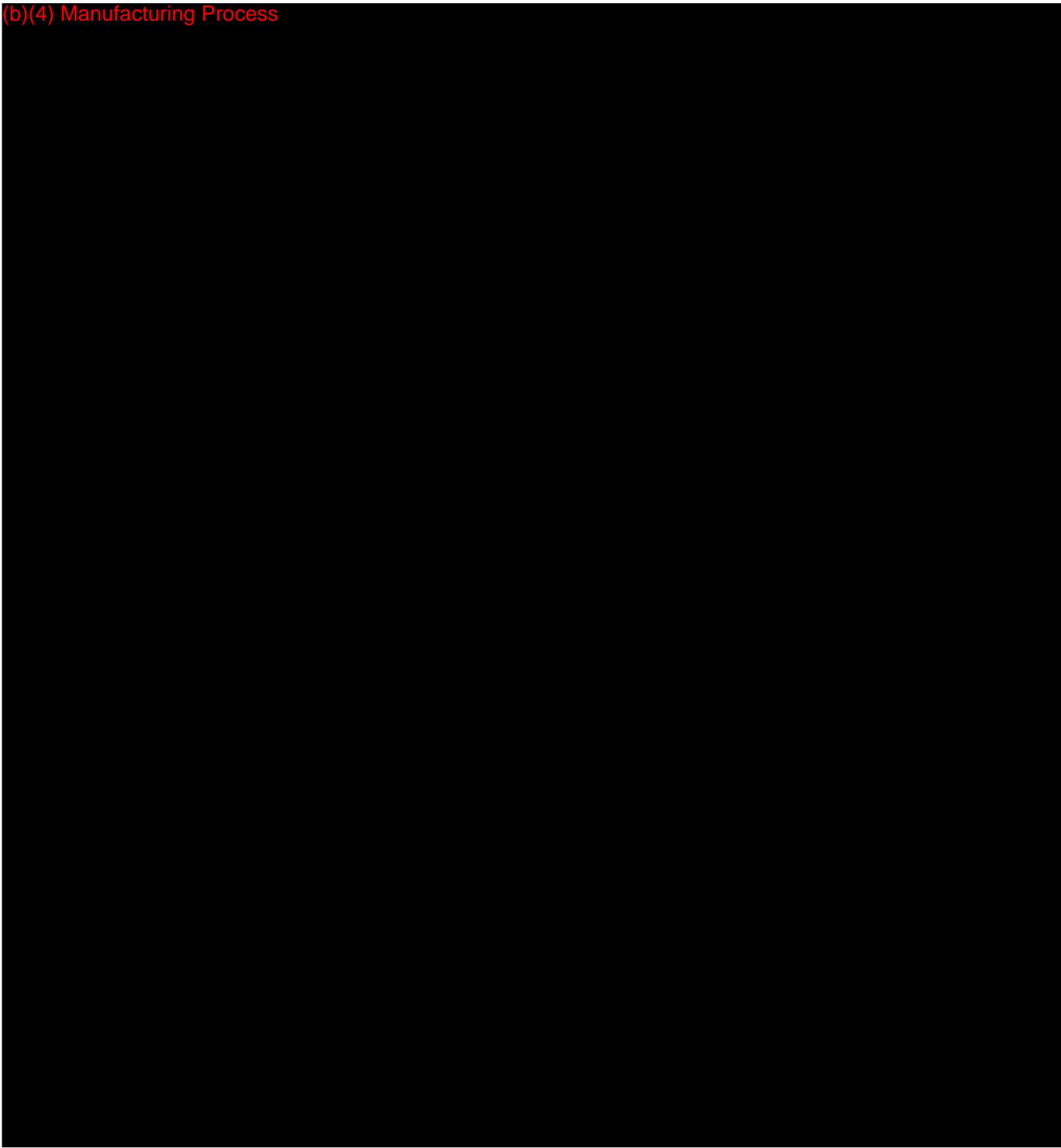
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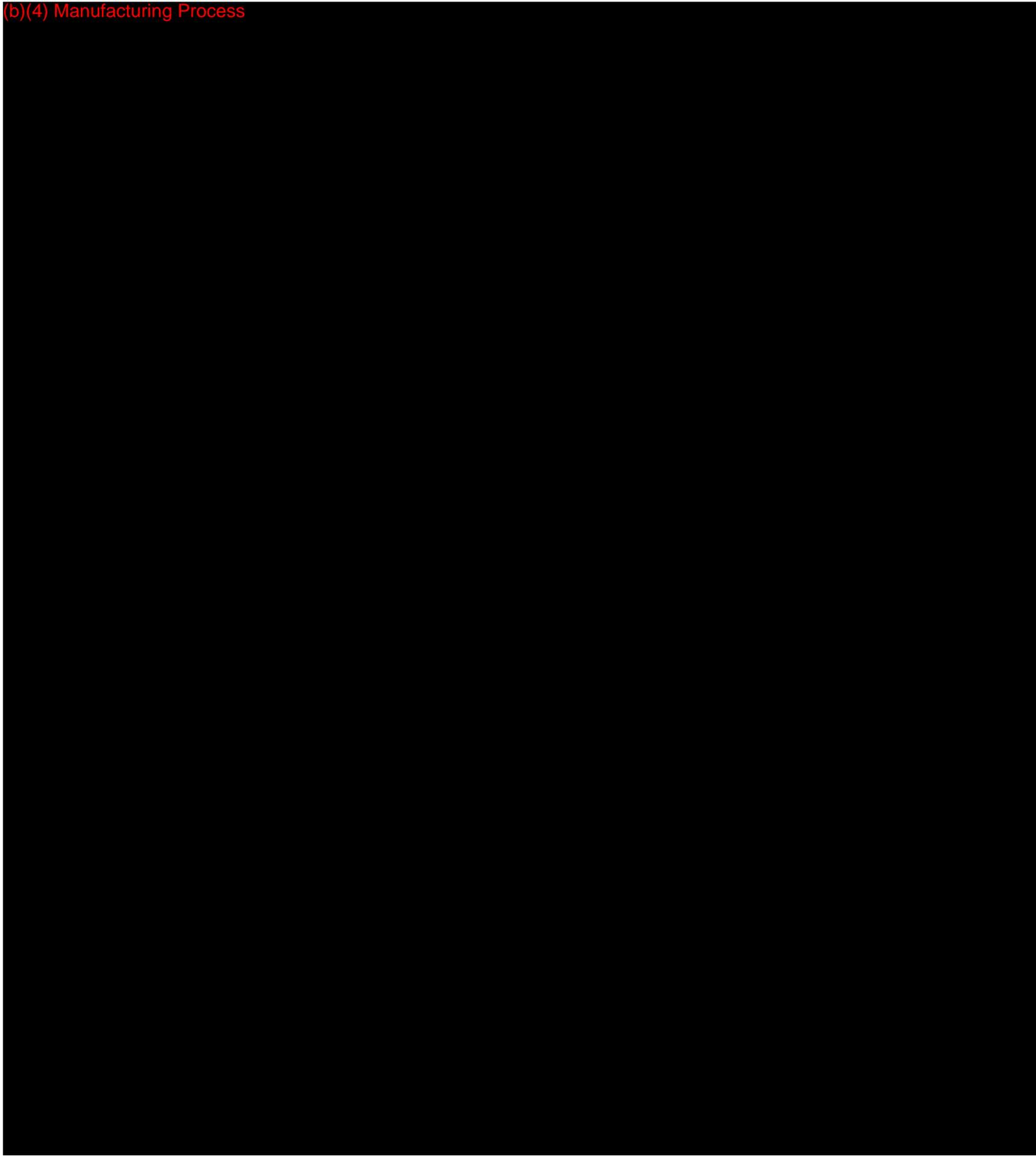
## 2 Production Process Description

An exploded view of the product is shown below.

(b)(4) Manufacturing Process



(b)(4) Manufacturing Process



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### 3 Packaging

SCCM US were packed in retail boxes as normal production items. They were repacked by (b)(4) for sterilisation (see section below)

Table 5. Overview of the packaging process – IFU / Info cart, numbers and site (Part 1)

Packing info:	Info cart	IFU	Number of items in retail box	Where packed
Production ID:				



**Table 6. Overview of the packaging process – Item numbers and amount used (Part 2)**

Packing info: Production ID:	Retail box	Front label	Backside label	Closing label	Shipper box
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(b)(4) Manufacturing Process

#### 4 Sterilisation

Table 2 shows the details from the sterilisation process.

(b)(4)

**Table 7. Details of the sterilization process**

Sterilisation info: Production ID:	Packaging for sterilisation	Sterilisation certificate	Sterilisation method	Date and site of sterilisation
---------------------------------------	-----------------------------	---------------------------	----------------------	--------------------------------

(b)(4)

#### 5 Material Description – Traceability

SCCM US was assembled on (b)(4) with the item number (b)(4) 8 and Lot number (b)(4)

**Table 8. Identification of material used for the SCCM US catheter coating process**

Technicians (b)(6)		Date: (b)(4)		
Material:	Supplier:	Lot no:	Item no.:	Expiry date
(b)(4)				

**Table 9. Identification of material used for the SCCM US assembly process**

Technicians (b)(6)		Date: (b)(4)		
Material:	Supplier:	Lot no:	Item no.:	Expiry date
(b)(4)				

**Table 10. Identification of material used for the SCCM US packing process**

Technicians: (b)(6)		Date: (b)(4)		
Material:	Supplier:	Lot no:	Item no.:	
(b)(4)		N/A	(b)(4)	
(b)(4)		N/A	(b)(4)	

## 6 Change Log

In table 3 changes to this document are described as well as the reason for the change.

**Table 3. Change Log**

Version No.	Initials Issue Date (Month Year)	Short description of and reason for change
0.1	(b)(4)	(b)(4)
0.2		

## 7 Appendix 1 – Materials used for assembly



Raw IC  
information.pdf

## 8 Appendix 2 – Process parameters: Coating

Photos from the process parameters from the (b)(4) process.

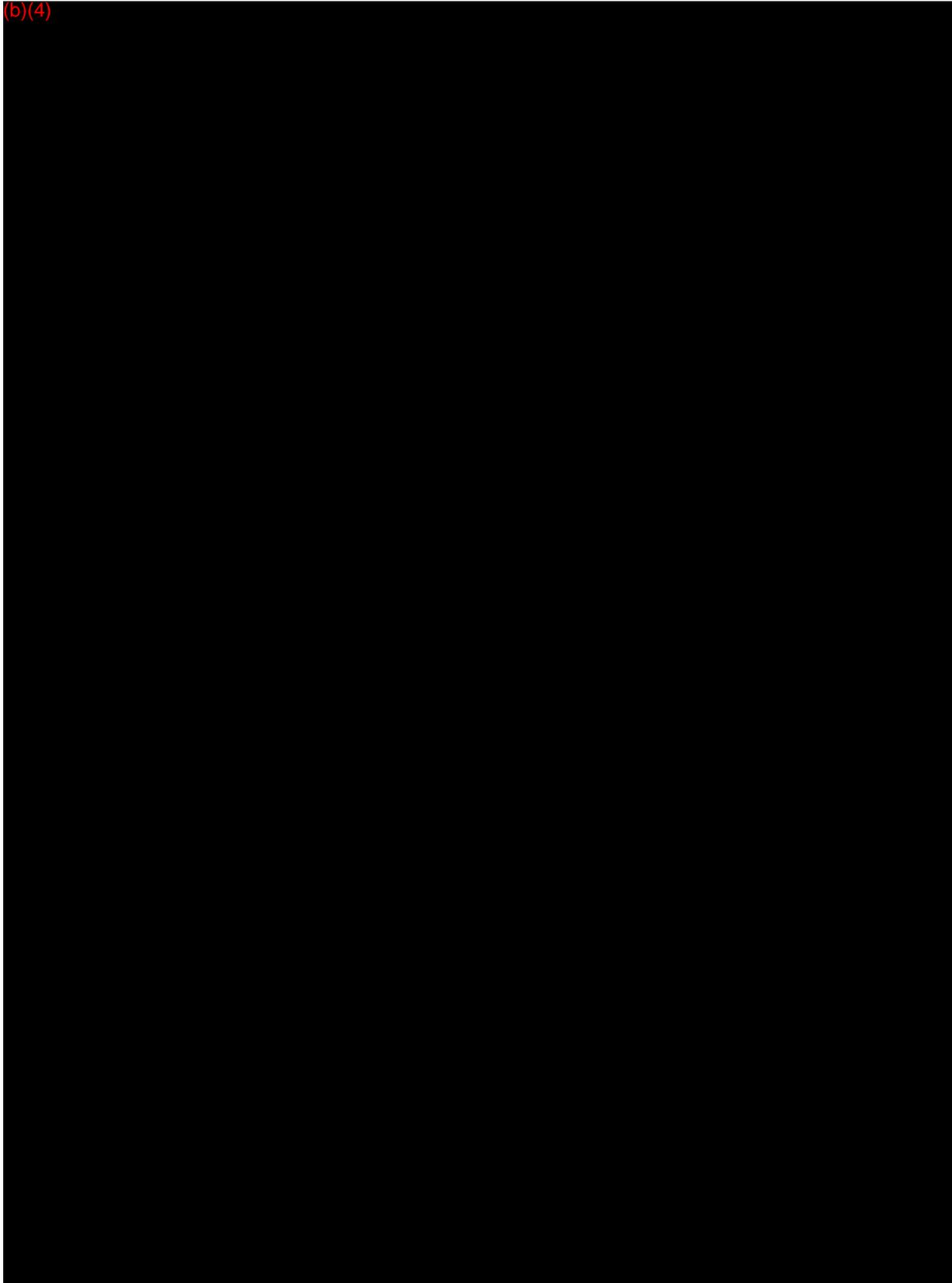
## 9 Appendix 3– Sterilization document

Certificate from (b)(4)



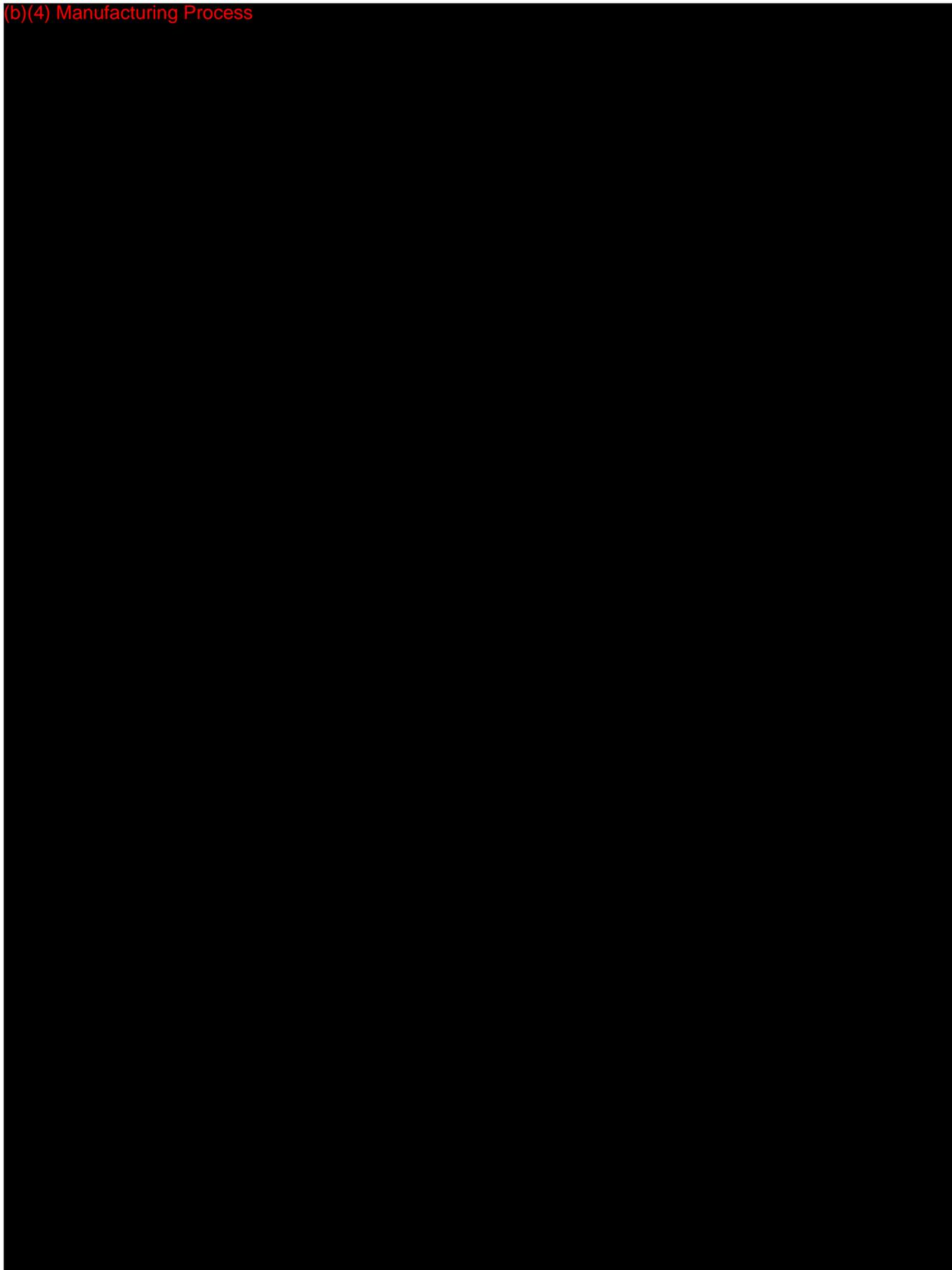
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certificate.pdf

(b)(4)



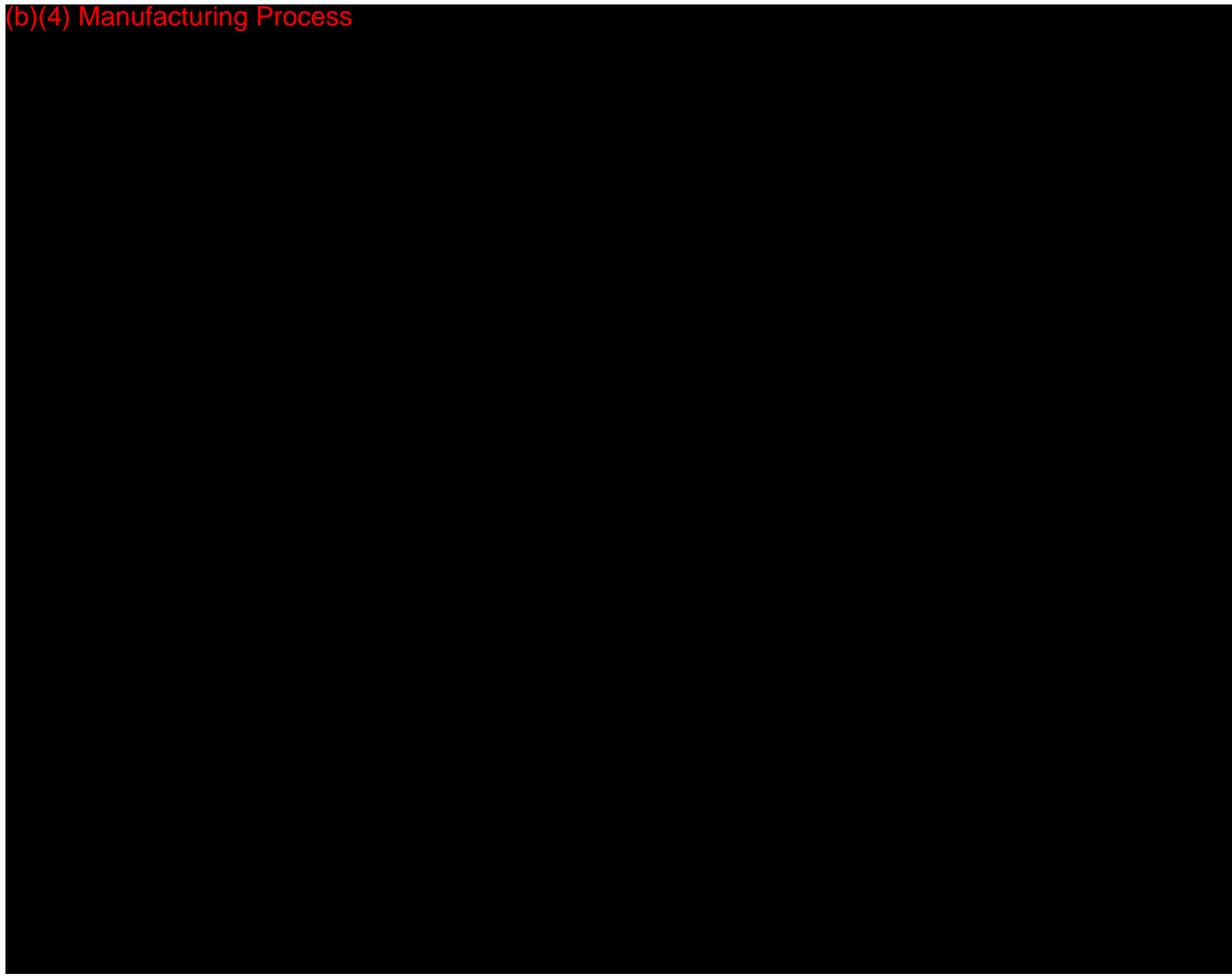
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(b)(4) Manufacturing Process



**CONFIDENTIAL**

(b)(4) Manufacturing Process



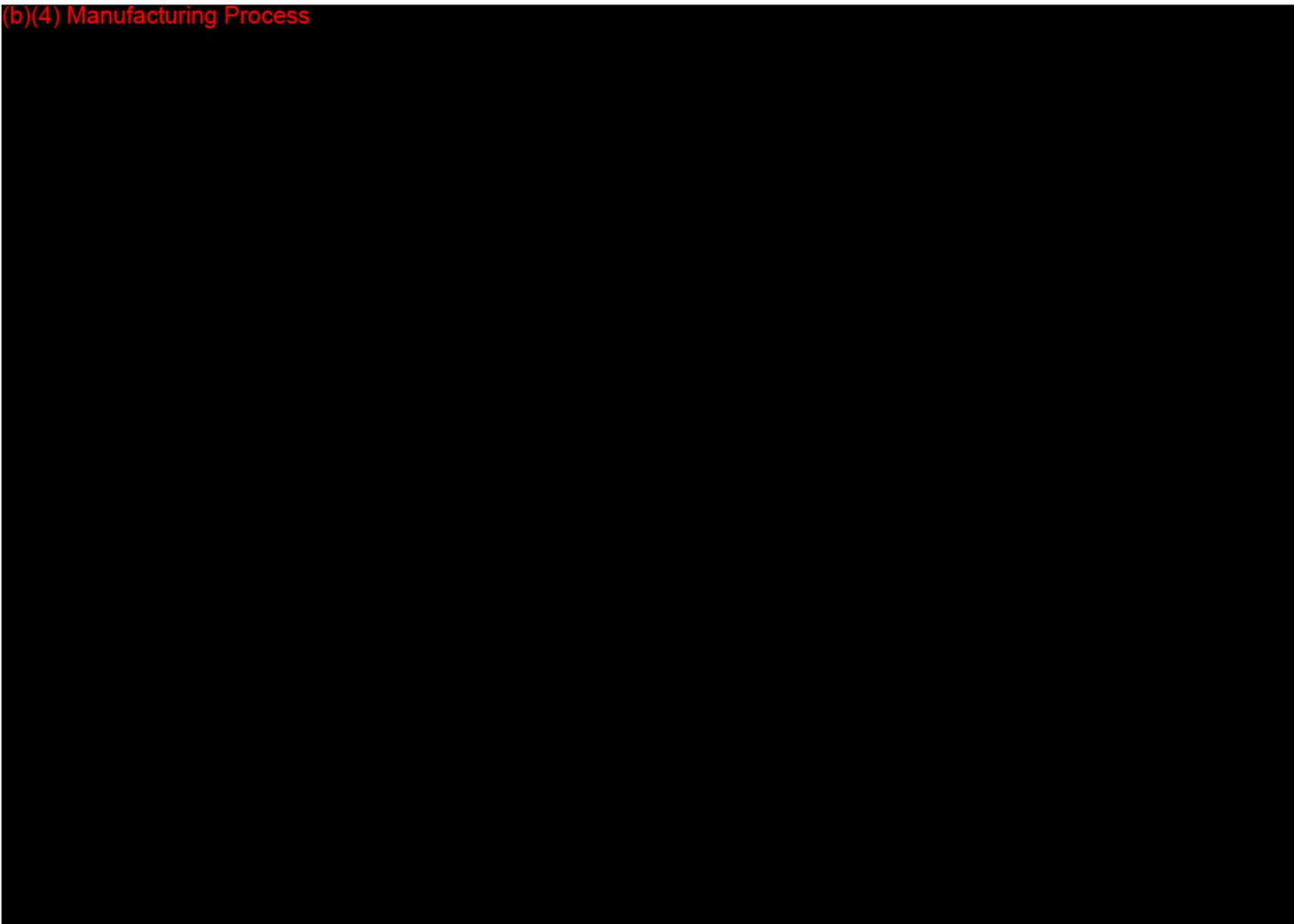
**CONFIDENTIAL**

(b)(4) Manufacturing Process



(b)(4) Manufacturing Process

(b)(4) Manufacturing Process



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Page (b)(4)

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Page 114 of 270

Laboratory Report

Doc ID (b)(4)

Version: (b)

Doc status: Approved

## SIGNATURE PAGE

Date (GMT)	Signed by
2014/09/11 06:51:09	(b)(6)
Justification	QA Project Manager
2014/09/11 11:45:00	(b)(6)
Justification	Regulatory Affairs Manager
Justification	

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# Stability Study Protocol

Study Type: Shelf life (design change)

SpeediCath Compact Male for US

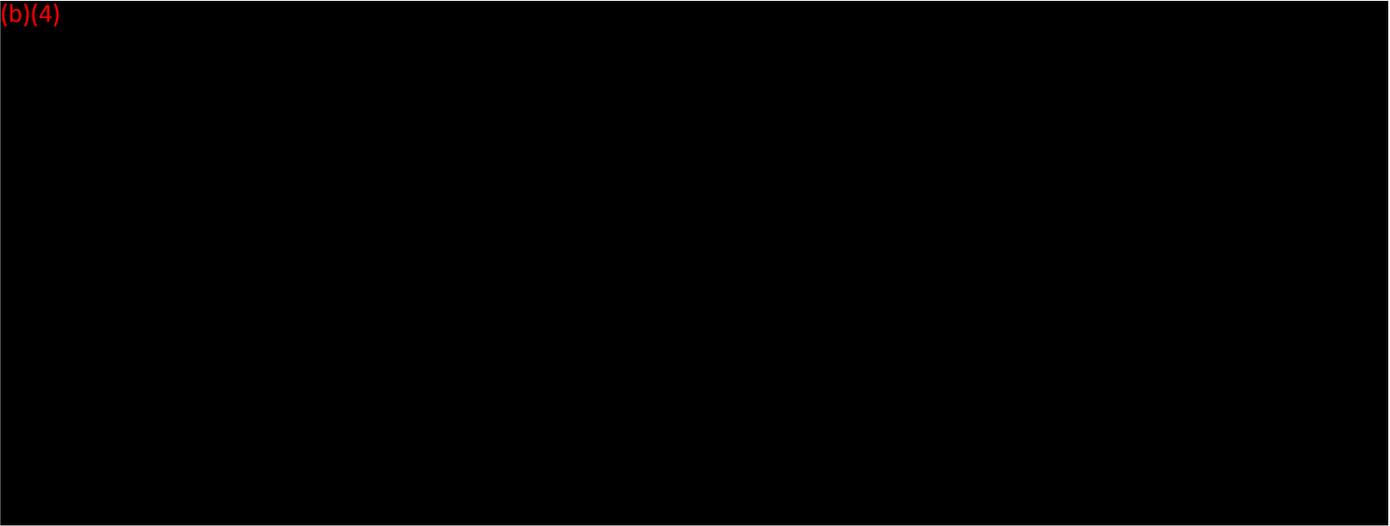
Stability study No.: (b)(4)

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## 1 Purpose

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## 2 Background

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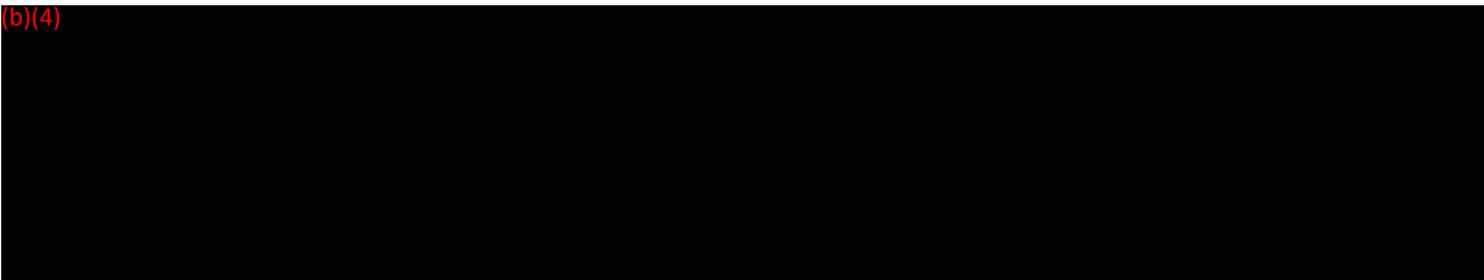
## 3 Responsibilities for the Study

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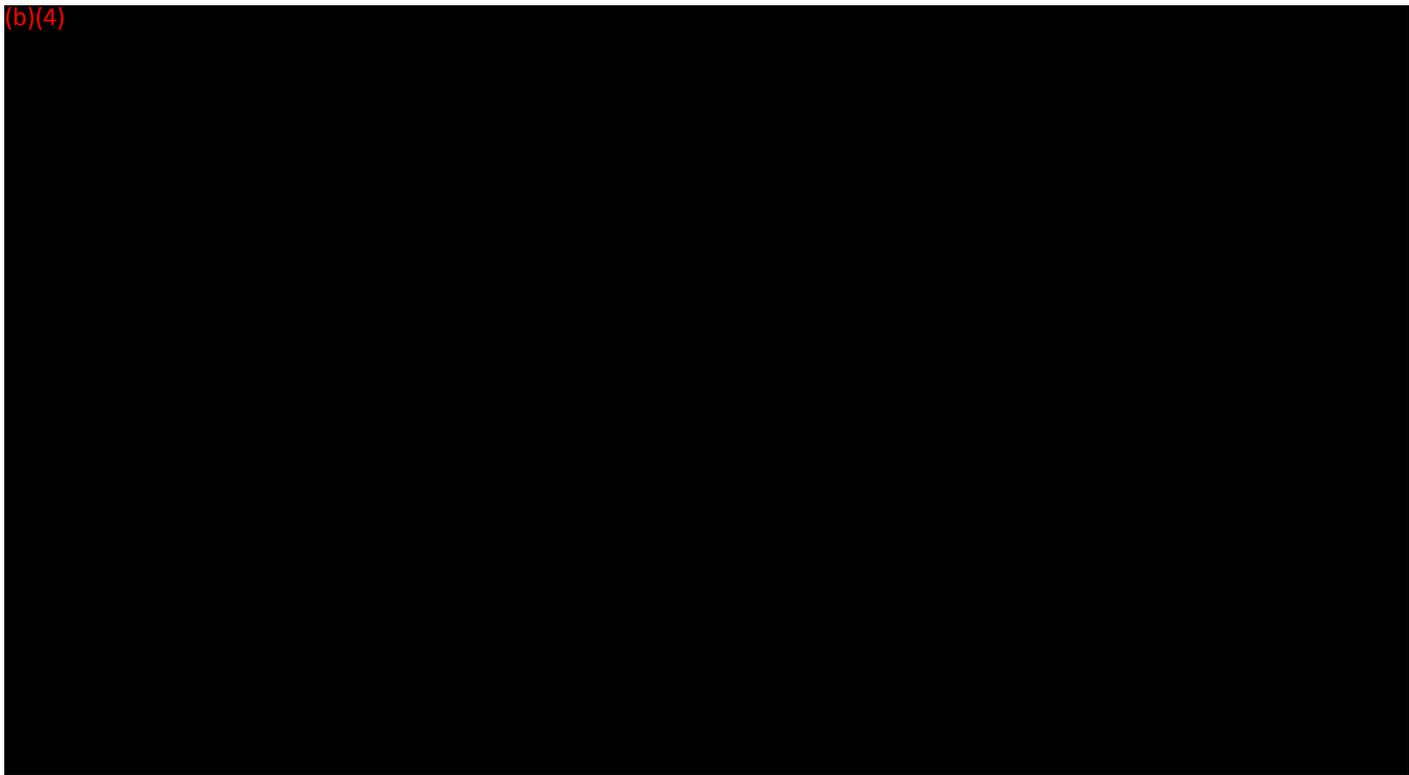


## 4 Description of Product/Material

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## 5 Study set-up

(b)(4)



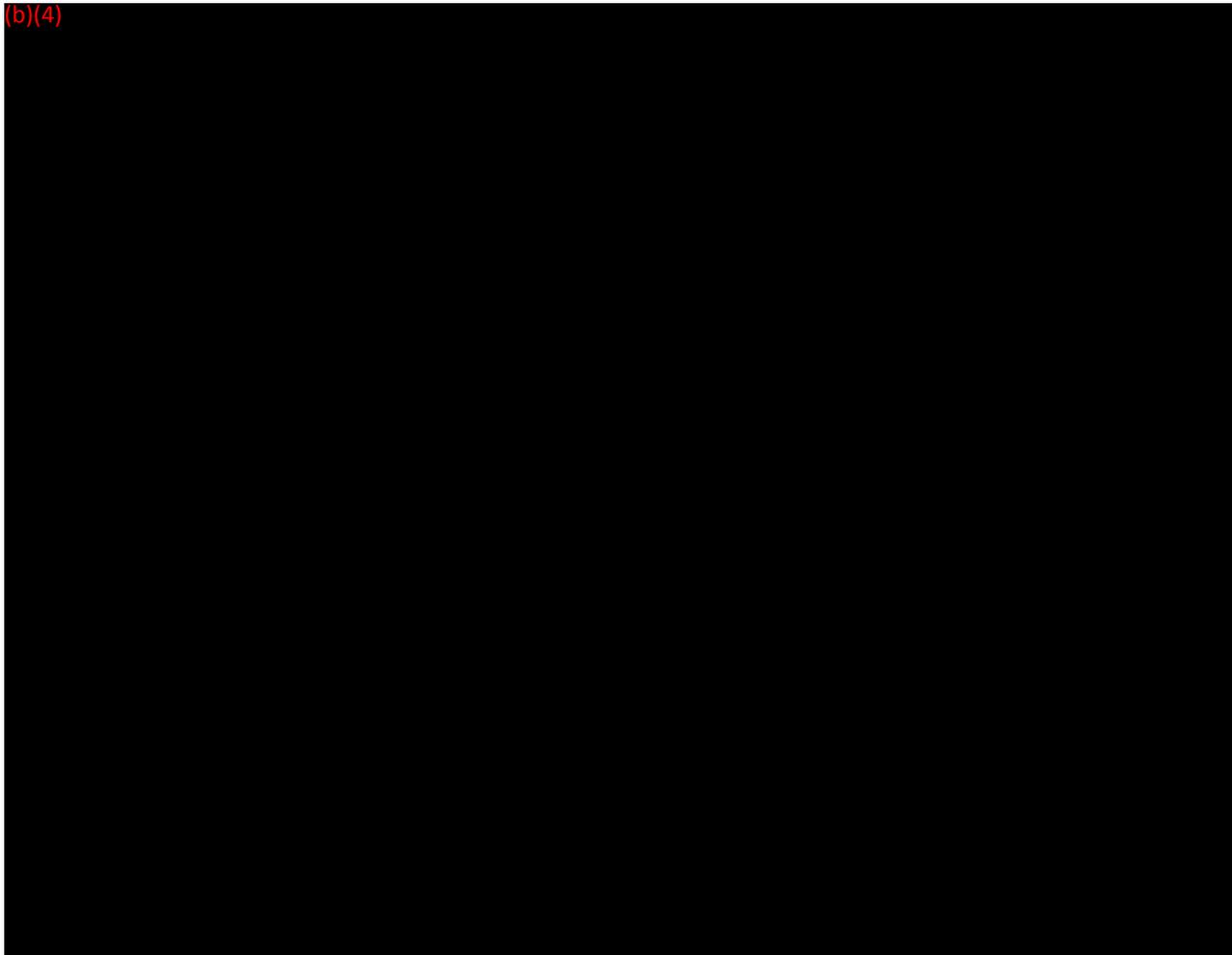
### 5.1 Preparation of Samples

#### 5.1.1 Labeling

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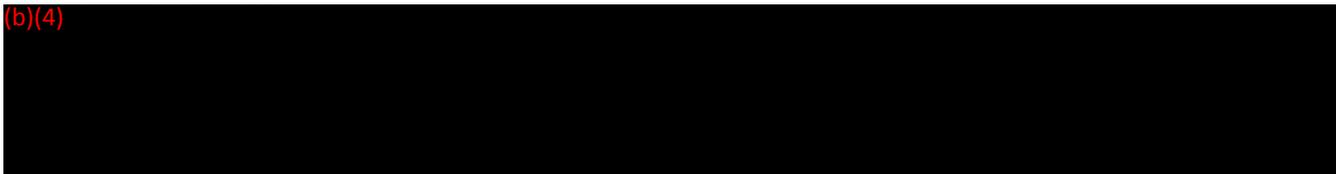


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### 5.1.2 Sterilization

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### 5.1.3 Storage Geometry

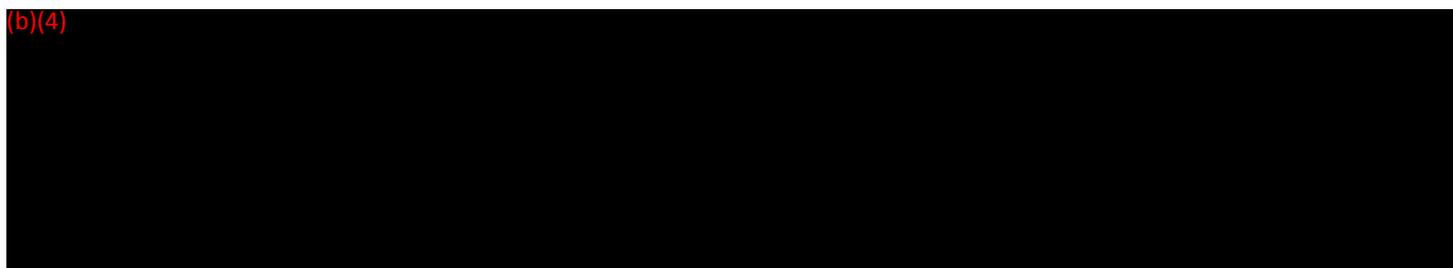
(b)(4)



## 5.2 Storage Conditions

### 5.2.1 Storage and Duration

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### 5.3 Inclusion of Lots

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### 5.4 Tests

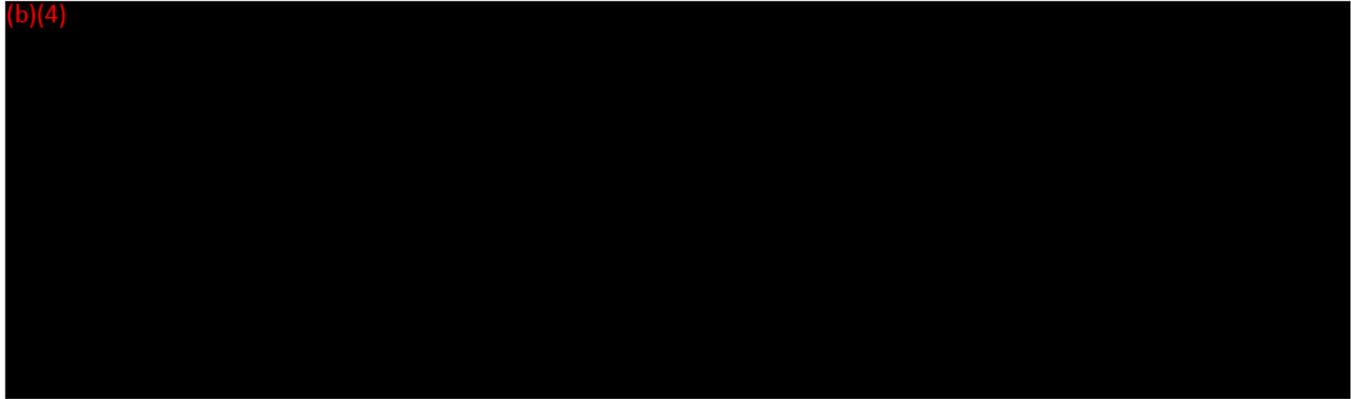
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### 5.5 Testing Frequency

#### 5.5.1 Overall Sampling Points

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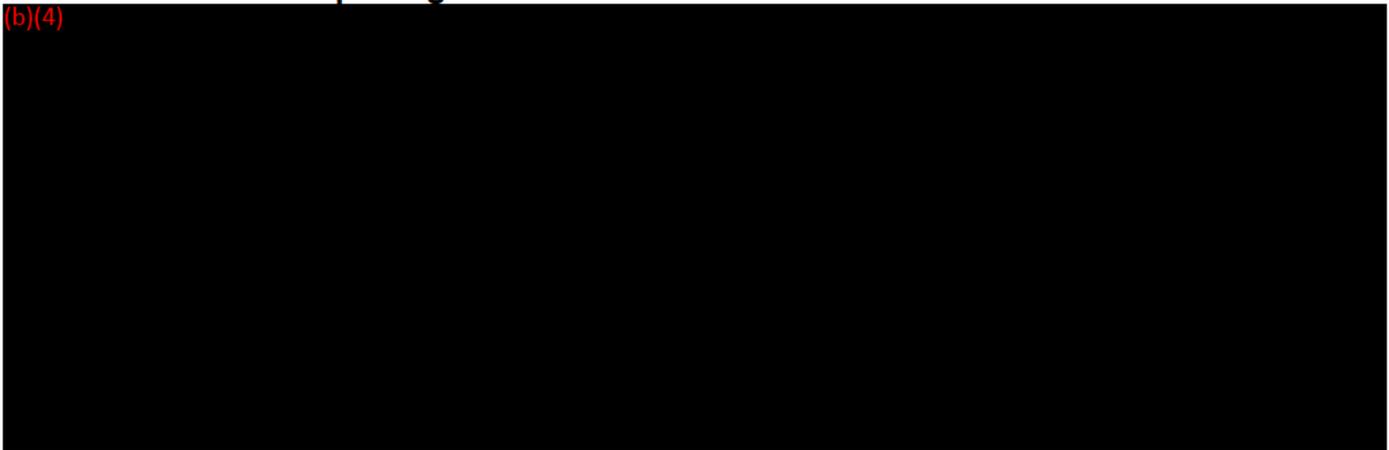
## 6 Protocol Deviations and OOS Results

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## 7 Data and Reporting

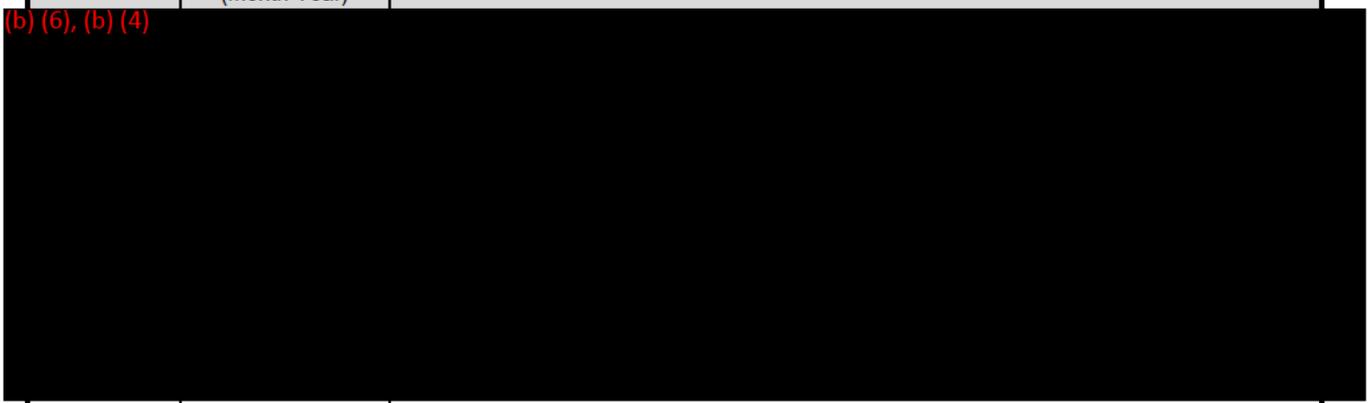
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## 8 Change Log

Version No.	Initials Issue Date (Month Year)	Short description of and reason for change
-------------	--	--

(b) (6), (b) (4)



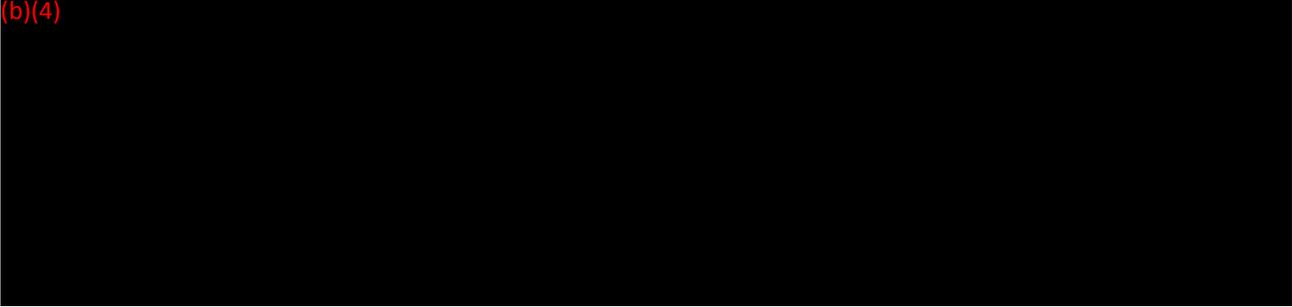
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## 9 References

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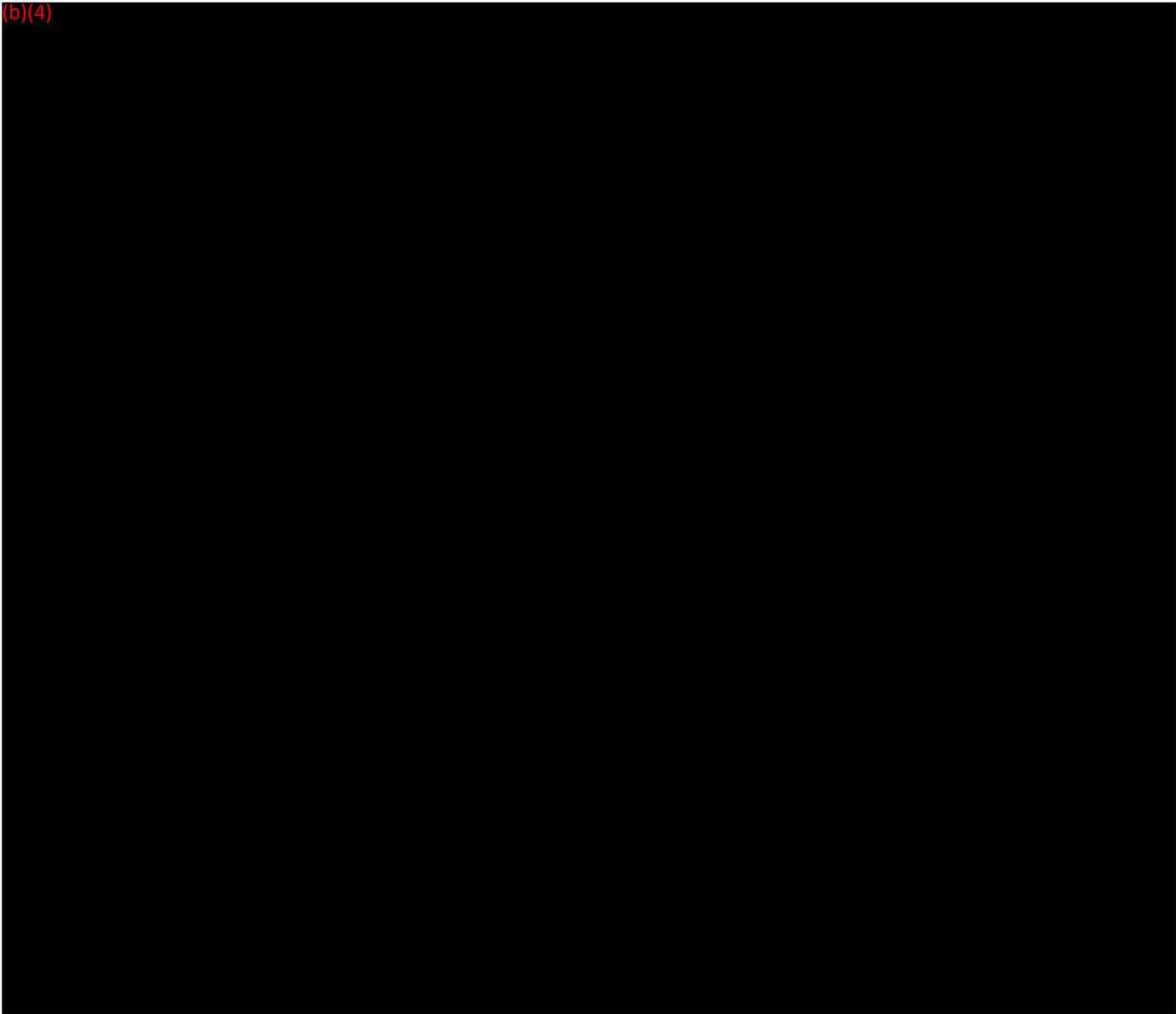
**10 Appendix 1. Product Composition**

(b)(4)



**11 Appendix 2. Calculation of Accelerated Aging**

(b)(4)



(b)(4)

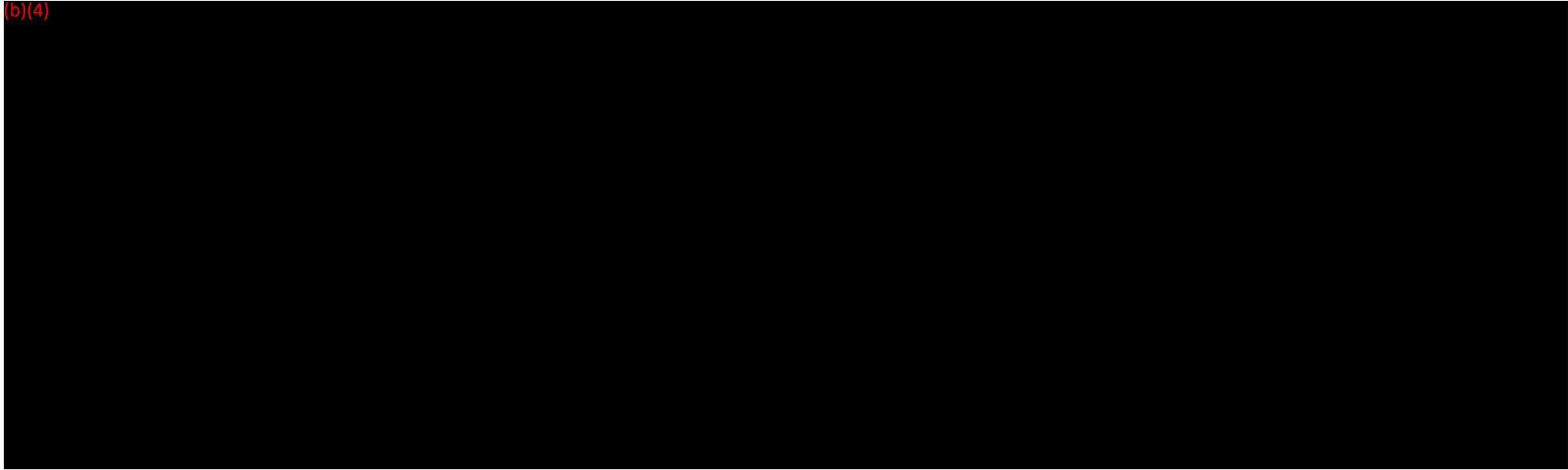


## 12 Appendix 3. Record tables (data sheets)

(b)(4)



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## SIGNATURE PAGE

Date (GMT)	Signed by
2014/10/14 08:29:27	(b)(6)
Justification	'Issuer, QA Project Manager'
2014/10/14 10:26:59	(b)(6)
Justification	'Sr. Product Support Specialist, Approver'
Justification	

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# Stability Study Report

Study Type: Shelf life (design change)

Shelf life

(b)(4)

(b)(4)

Stability study no.

(b)(4)

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## 1 Summary

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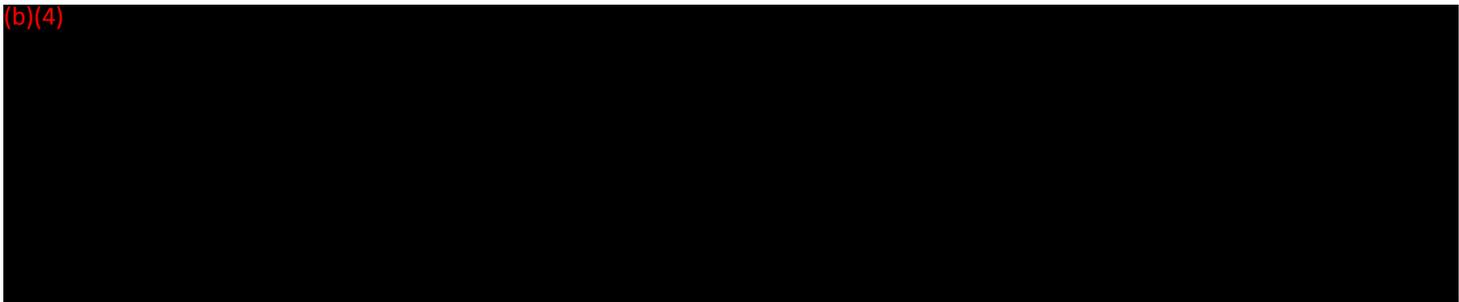
## 2 Purpose

(b)(4)



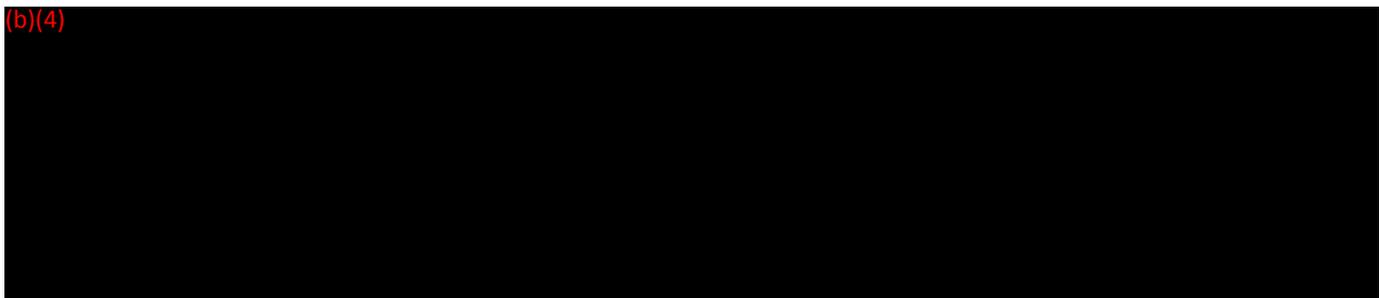
## 3 Description of Product/Material

(b)(4)

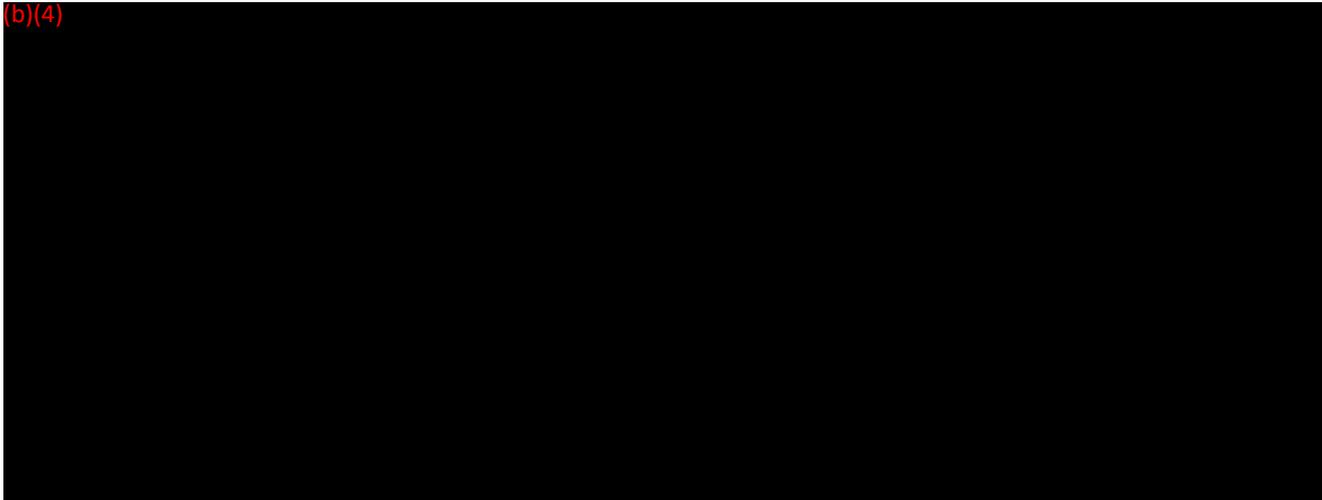


## 4 Study Set-up

(b)(4)

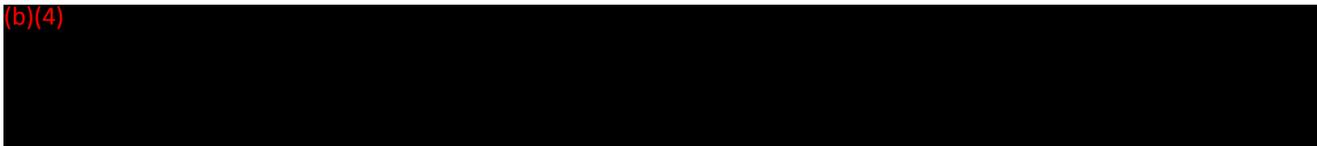


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## 5 Protocol Deviations

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## 6 Results

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## 7 Out of Specification (OOS) Results

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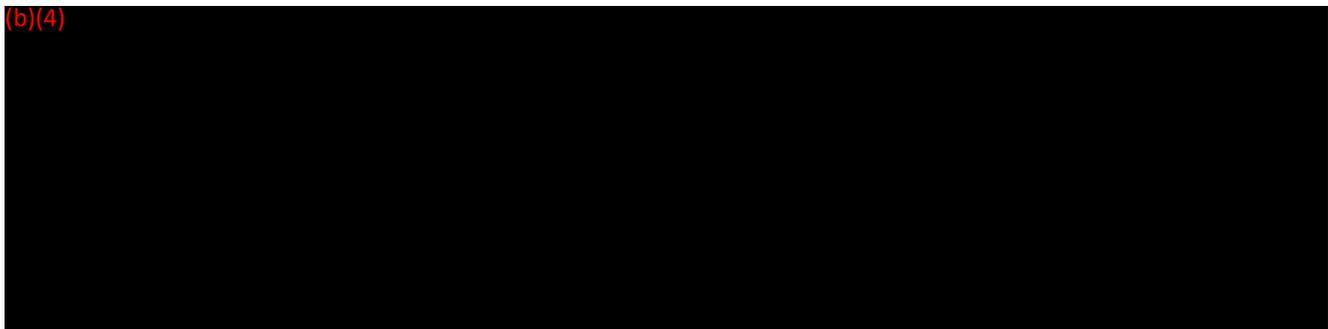
## 8 Discussion

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## 9 Conclusion

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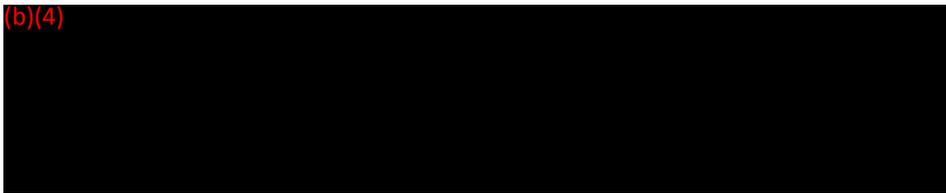
## 10 Change Log

(b)(4)



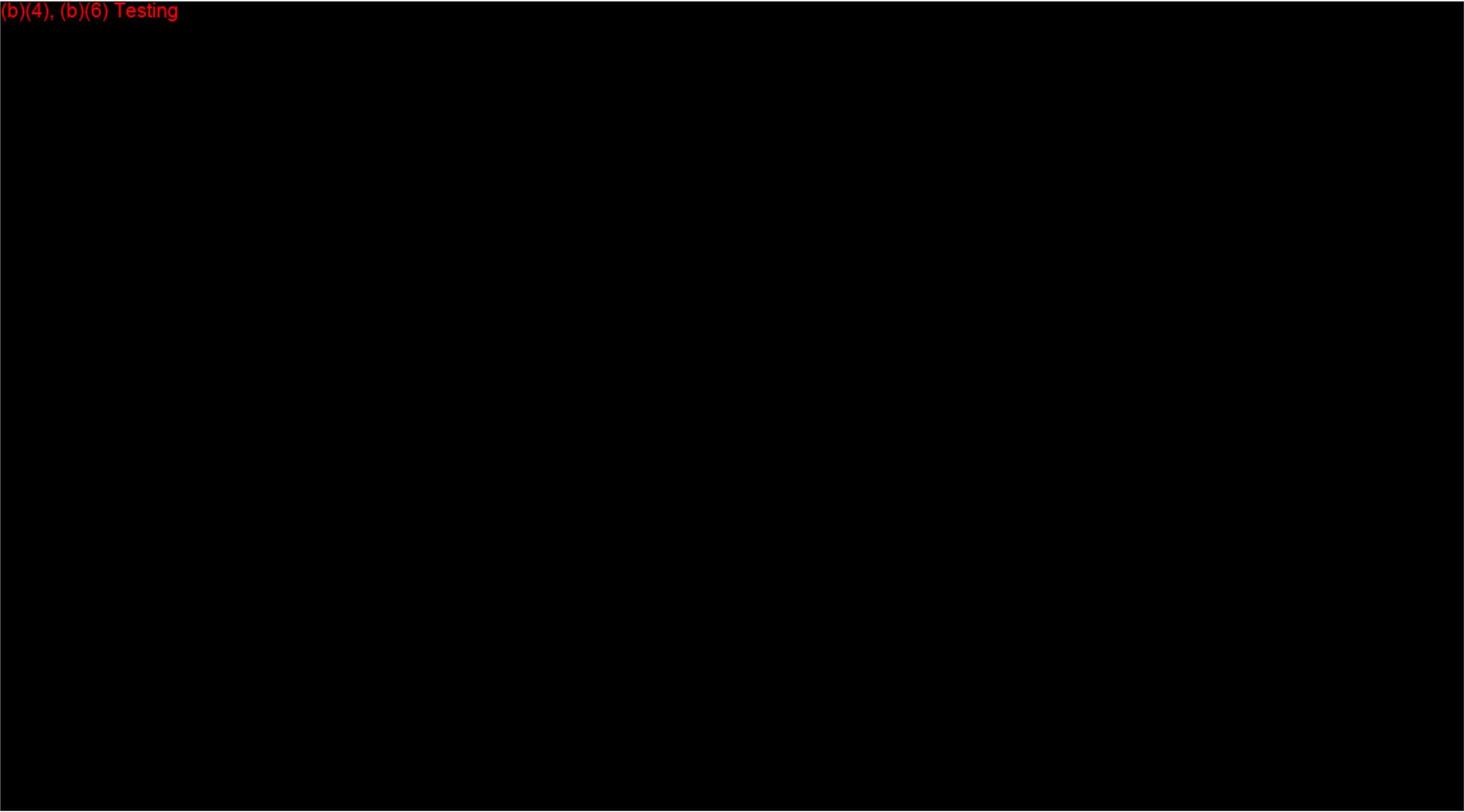
## 11 References

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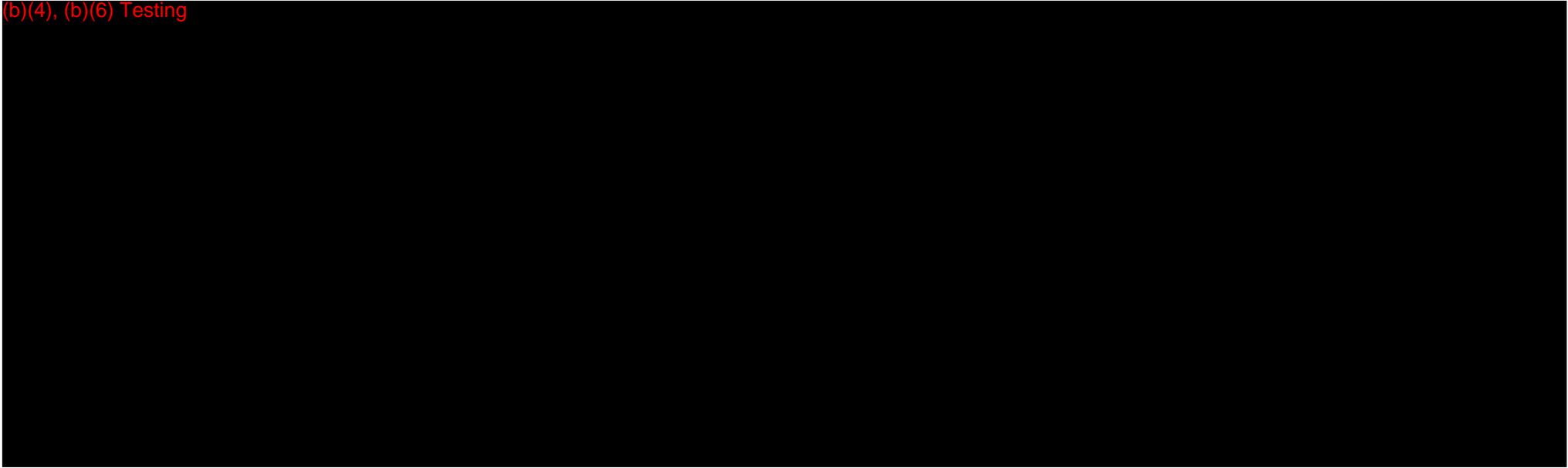


## 12 Appendix 1 Record tables

(b)(4), (b)(6) Testing

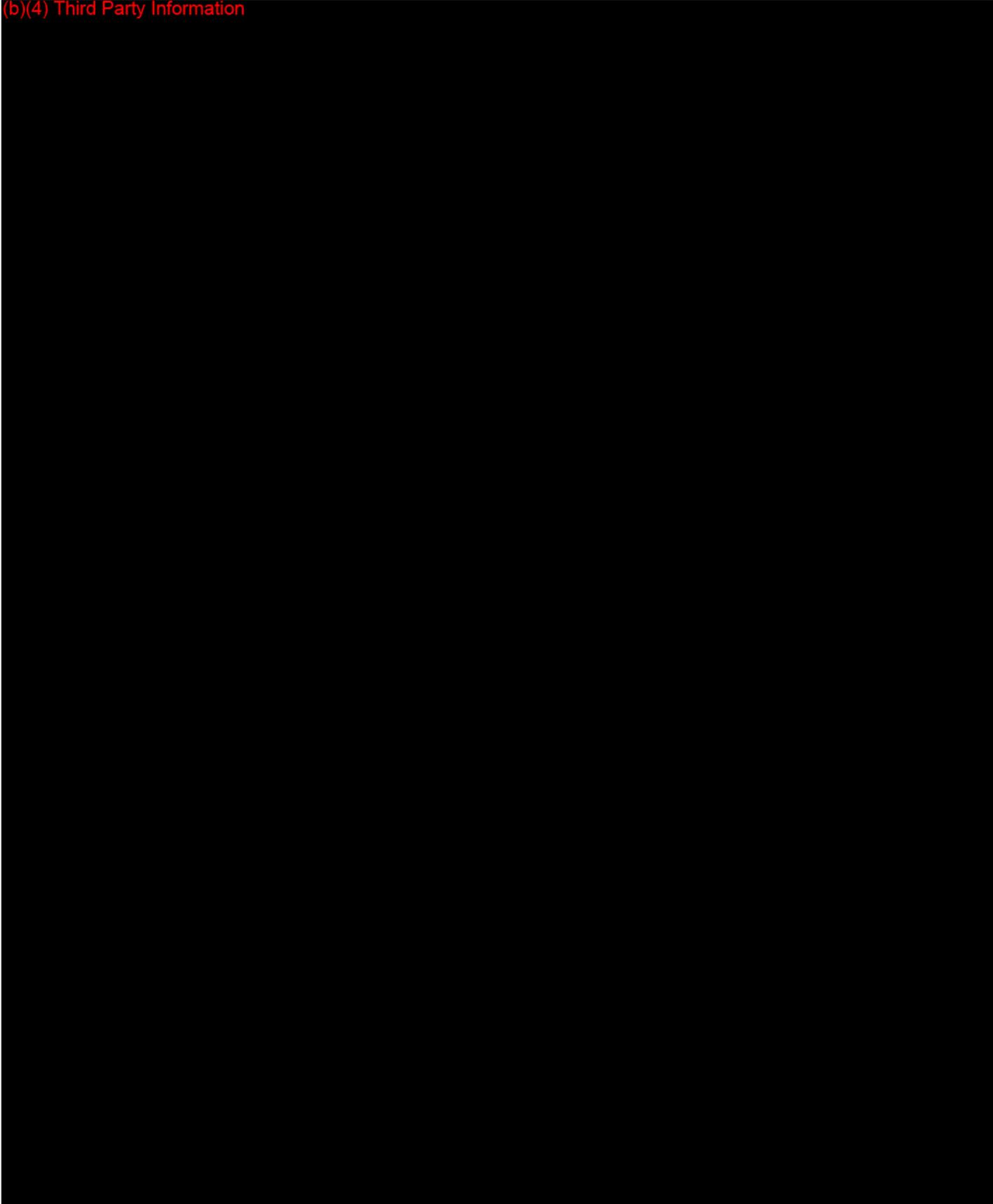
A large, solid black rectangular redaction box covers the majority of the page content, obscuring all text and graphics that would otherwise be present.

(b)(4), (b)(6) Testing



### 13 Appendix 2: Sterilization certificate

(b)(4) Third Party Information



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Date (GMT)	Signed by
2014/10/15 06:37:32	(b)(6)
Justification	'Issuer, QA Project Manager'
2014/10/15 08:19:41	(b)(6)
Justification	'Sr. Product Support Specialist, Approver'
Justification	

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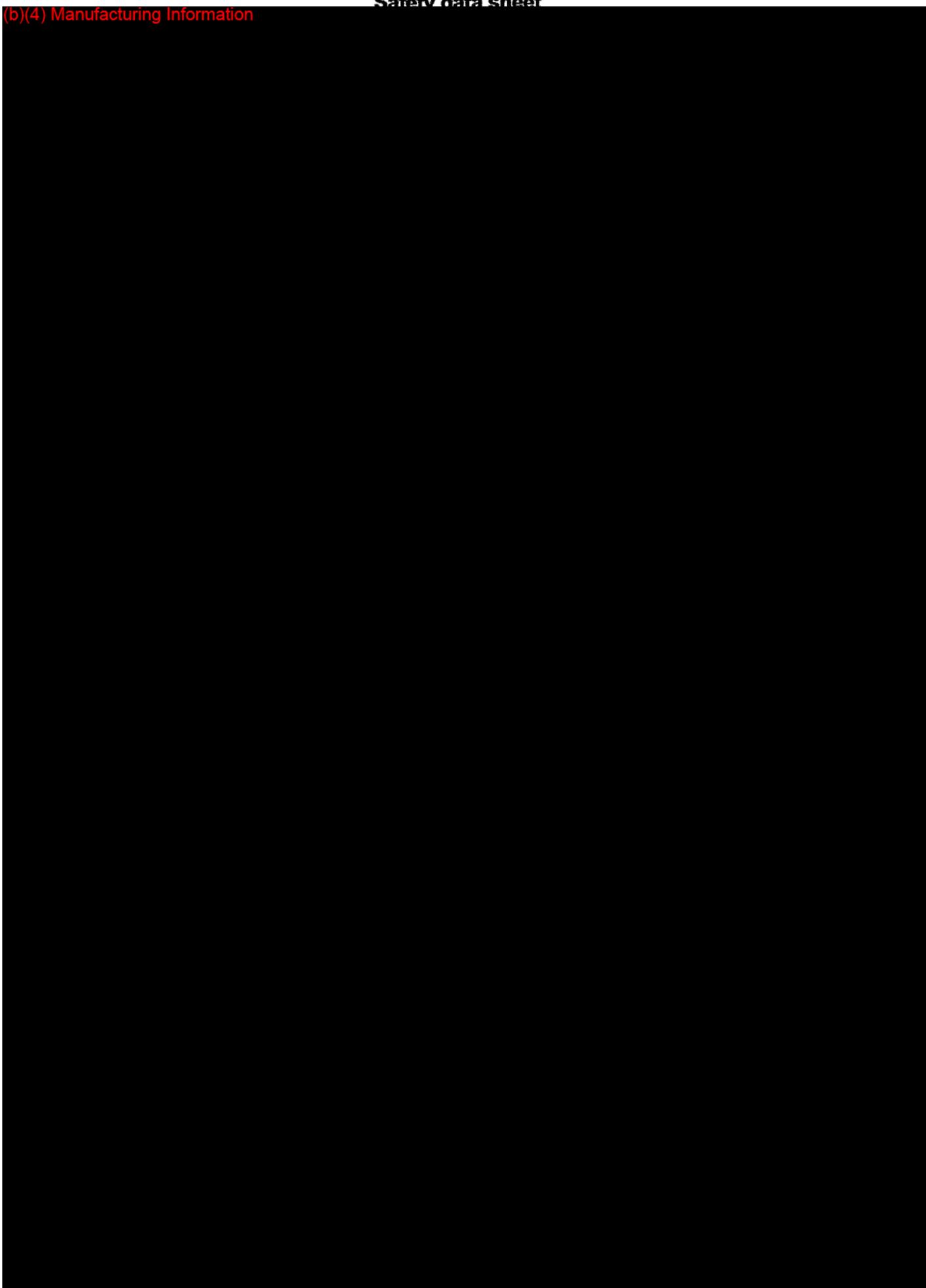






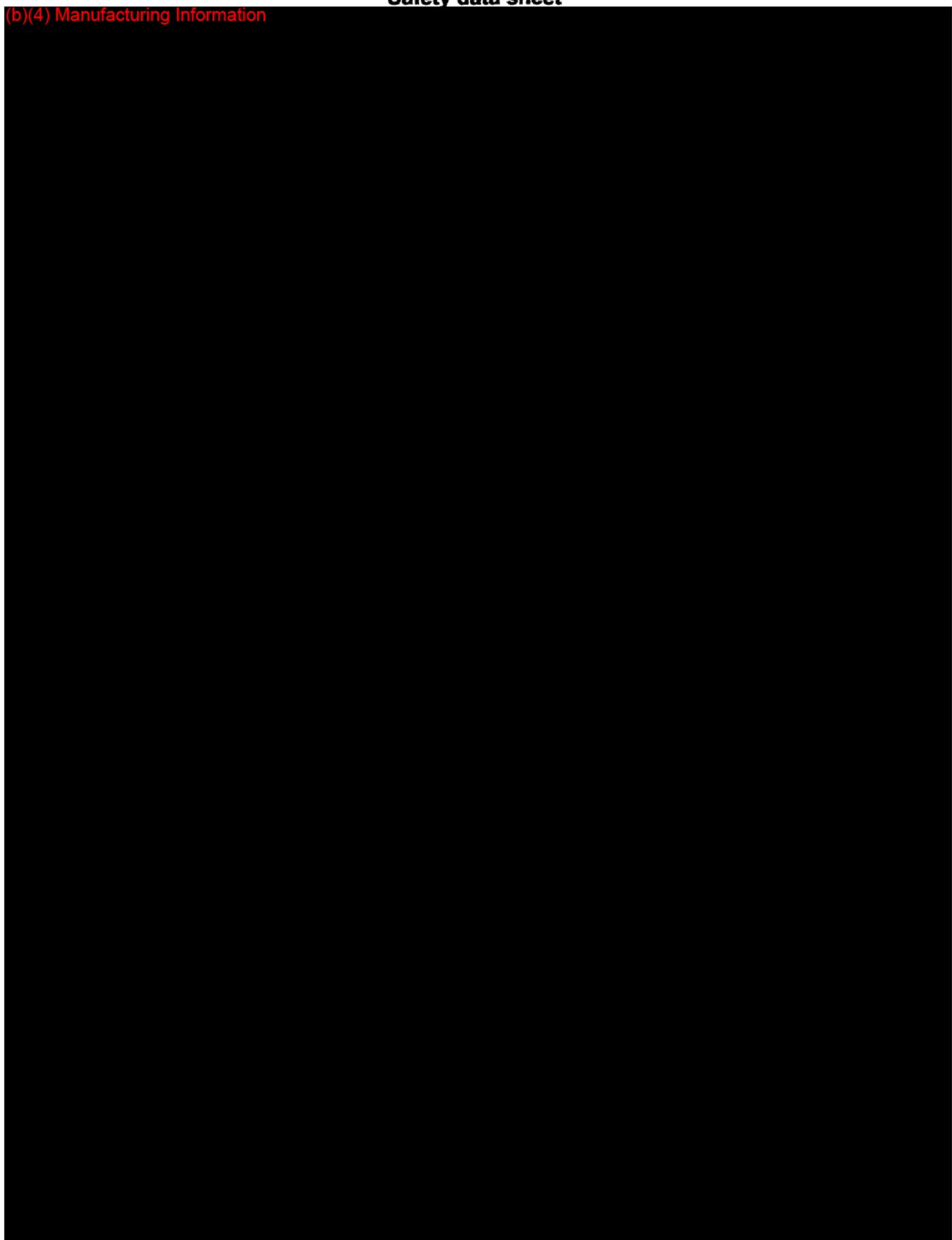
**Safety data sheet**

(b)(4) Manufacturing Information



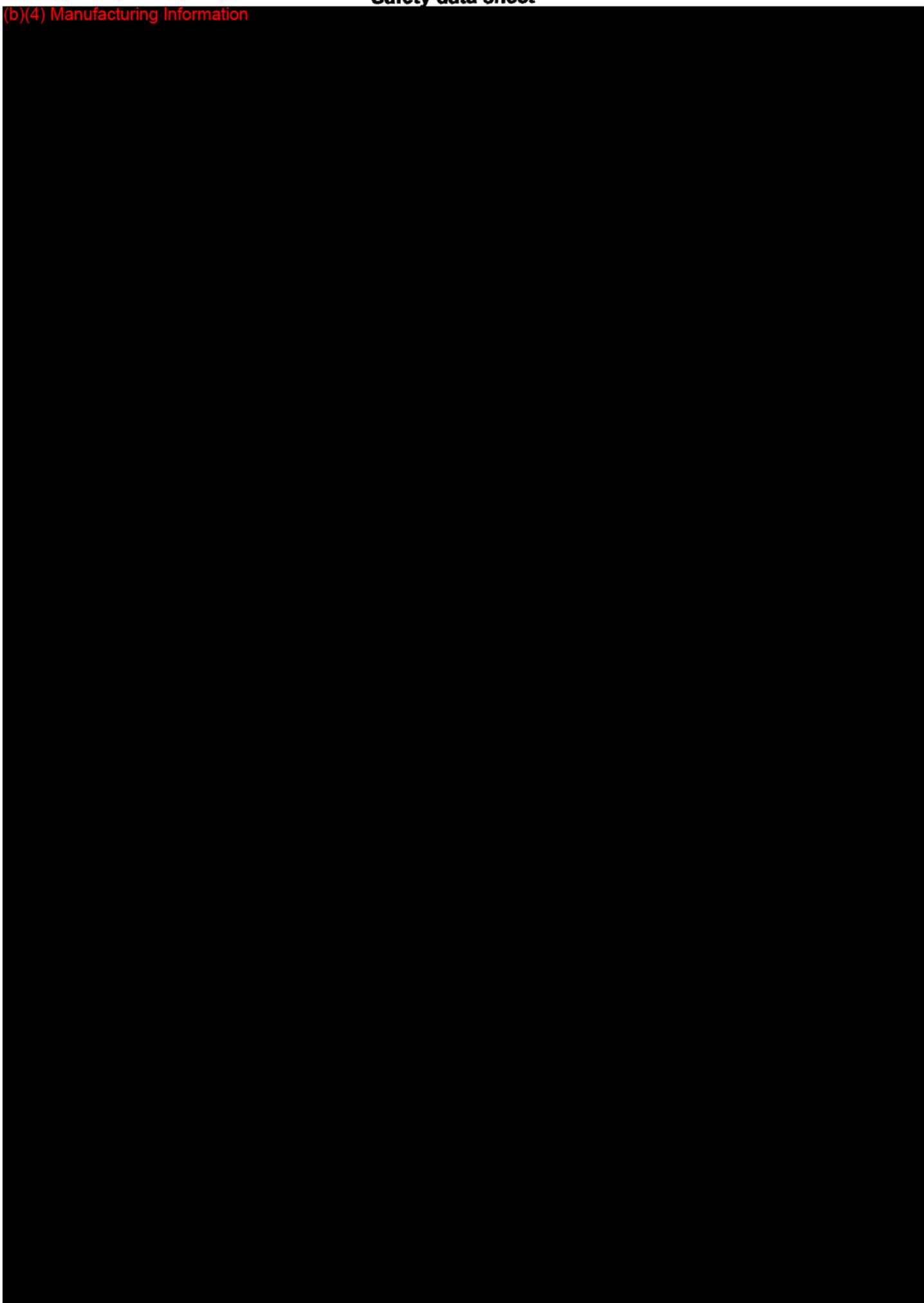
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(b)(4) Manufacturing Information



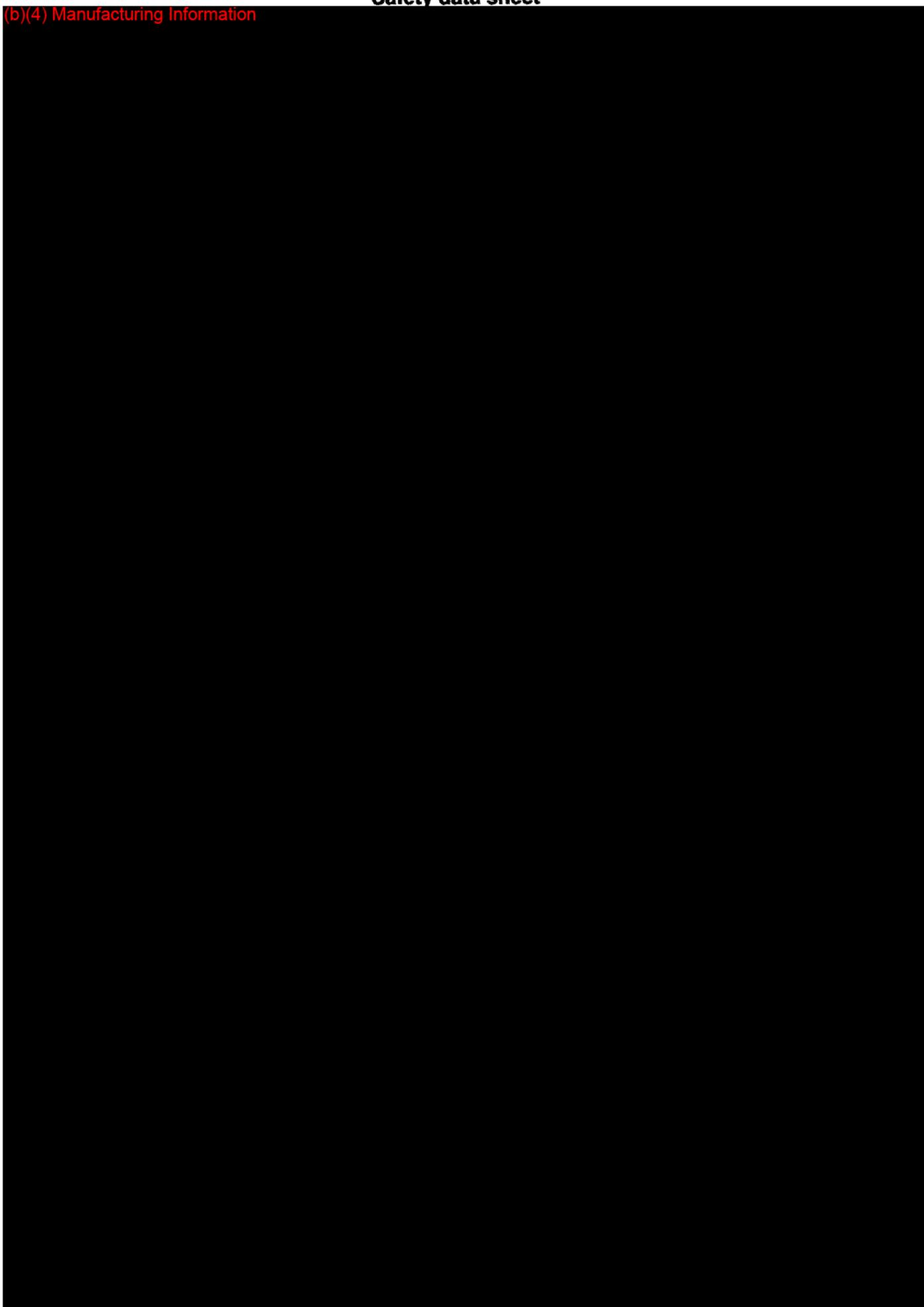
**Safety data sheet**

(b)(4) Manufacturing Information



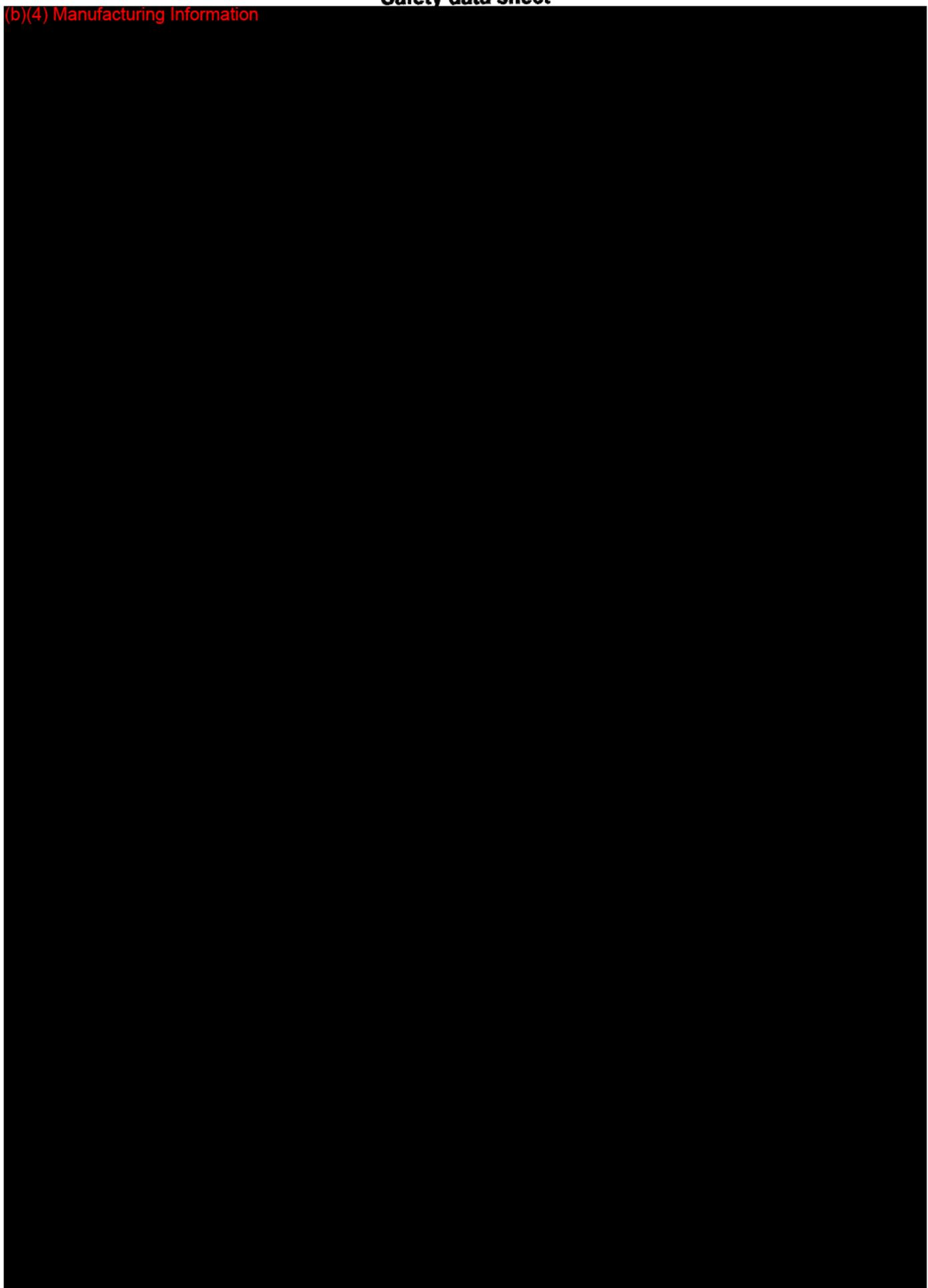
**Safety data sheet**

(b)(4) Manufacturing Information



**Safety data sheet**

(b)(4) Manufacturing Information



**Safety data sheet**

(b)(4) Manufacturing Information





























































































January 7, 2015

FDA CDRH DMC

JAN 08 2015

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Received

K143182/S001

**RE: 510(k) K143182/S001 Speedicath Compact Male**

To Whom It May Concern:

Coloplast A/S hereby submits the additional information to the 510k K143182/S001 for the Speedicath Compact Male. This request is provided in duplicate. In lieu of one paper copy, Coloplast is providing an electronic version copied to CD-ROM per FDA guidance "eCopy Program for Medical Device Submissions" dated October 10, 2013. The electronic copy is an exact duplicate of the paper copy.

Please contact me for questions or if you need further information.

Best regards,



Brian E. Schmidt  
Regulatory Affairs Manager  
Coloplast Corporation  
1601 West River Road N  
Minneapolis, MN 55411 USA

Office: (612) 302-4987  
Mobile: (612) 968-9567  
Fax: (612) 287-4138  
Email: [usb@coloplast.com](mailto:usb@coloplast.com)

1-CD  
30

January 7, 2015

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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Please contact me for questions or if you need further information.

Best regards,

A handwritten signature in black ink, appearing to read "Brian E. Schmidt", with a long horizontal flourish extending to the right.

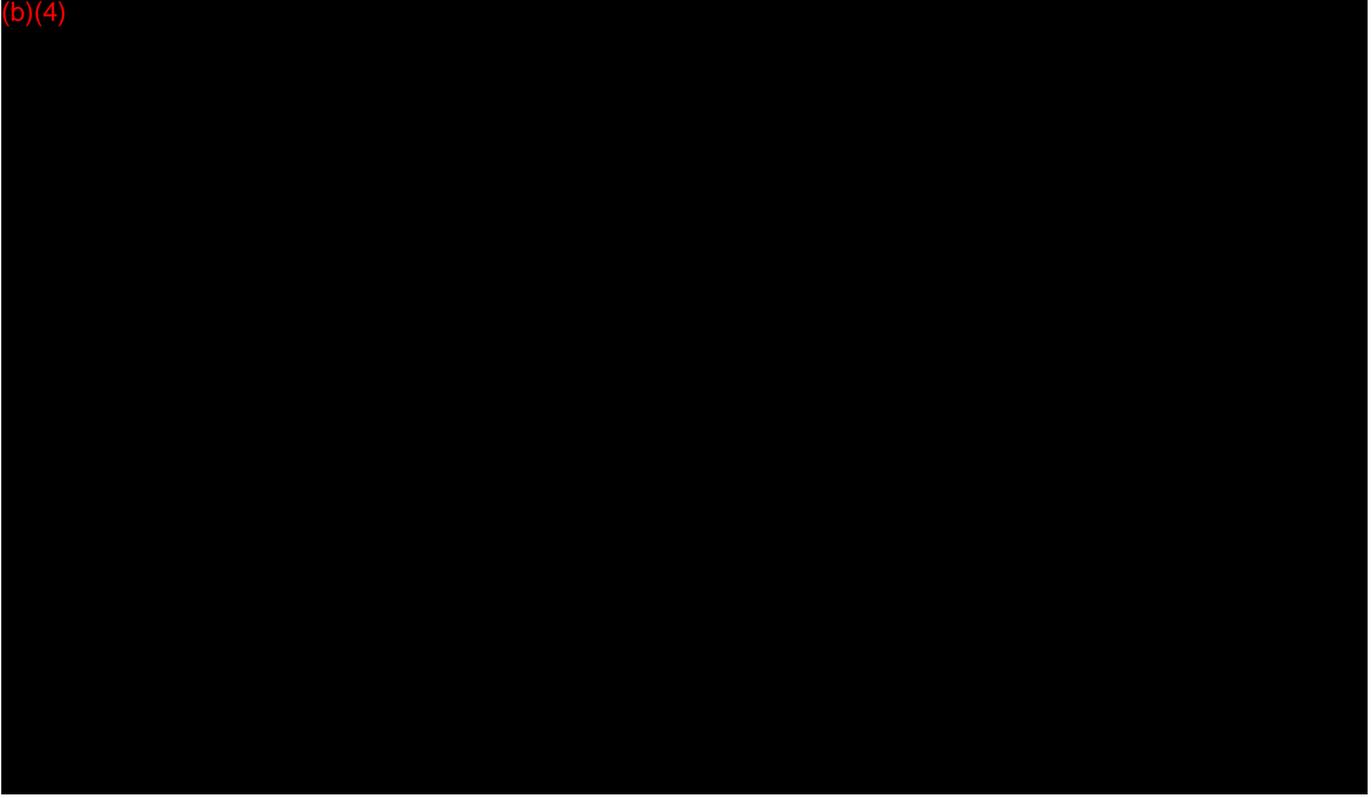
Brian E. Schmidt  
Regulatory Affairs Manager  
Coloplast Corporation  
1601 West River Road N  
Minneapolis, MN 55411 USA

Office: (612) 302-4987  
Mobile: (612) 968-9567  
Fax: (612) 287-4138  
Email: [usb@coloplast.com](mailto:usb@coloplast.com)

**K143182 Speedicath Compact Male (Coloplast)**

Deficiencies:

(b)(4)



**How to use**

SpeediCath Compact is developed for drainage of the bladder by intermittent catheterization.

This Compact catheter is designed especially for men. It is part of the unique SpeediCath family with its main focus being hygiene and safety. SpeediCath consists of a coated, ready-to-use catheter supplied in saline solution.

Start by washing your hands and the area around the urethral orifice. It is important to avoid transferring bacteria from your hands to the catheter.

Make sure you are completely ready to proceed with catheterization before you open the packaging. Complete the catheterization without undue delay and remove the catheter upon emptying the bladder.

**Instructions for use**

23315975 Version 1

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Manufacturer: Coloplast A/S  
 Høttedam 1, 3050 Humlebaek, Denmark  
 Distributed by: Coloplast Corp., 1601 W. River Rd. N, Minneapolis, MN 55411 USA  
 Fabricante: Coloplast A/S Høttedam 1 3050 Humlebaek Denmark

Product Evaluation  
 For customer service or to return product, please call: 1-800-533-0464 in USA.  
 Rx only  
 Evaluación del Producto  
 Para servicio al cliente o para devolver el producto, llame a: 1-800-533-0464 en EE.UU.

**Indication**

Urinary catheter for intermittent use.

The catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing the urine to drain. The catheter is for male patients.

**Information**

Coloplast accepts no liability for any injury or loss that may arise if this product is used in a manner contrary to Coloplast's current recommendations.

The catheter can be exposed to extreme temperatures (below 0°C and up to 60°C) for up to 24 hours without the catheter being damaged.

The solution in which the catheter is stored is harmless. However, the solution may stain.

Catheterization should take place as quickly as possible after opening the package. The catheter should always be removed when the bladder has been emptied.

**Cautions**

Do not use if package is damaged  
 Contact your health care professional before you perform self-catheterization for the first time.

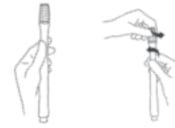
Contact your health care professional if you:

- have been diagnosed with urethral strictures.
- experience that the catheter does not drain the bladder the way you are used to.
- experience symptoms such as fever, discomfort when emptying the bladder, a frequent urge to urinate or blood in the urine.

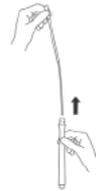
Federal (USA) law restricts this device to sale by or on the order of a physician. Inspect the catheter before use.

**Warning**

Reusing this single-use product may create a potential harm to the user. Reprocessing, washing, disinfection, and/or sterilization may compromise product characteristics, causing additional risk of physical harm to or infection of the user.



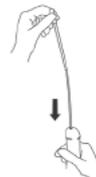
- 1) Hold the catheter vertically so the lid points upwards.
- 2) Open the packaging by twisting the lid. Make sure the lid is kept within reach.



- 3) Pull the white connector upwards to release the catheter.  
 The catheter is released when you hear a "click" and it is now ready to be used. Avoid touching the surface of the catheter – only touch the white connector and be sure to not to bend the catheter.



- 4) If possible, empty the water from the packaging in a toilet or sink before catheterization.



- 5) Lift the penis with one hand to straighten out the urethra. Do not squeeze the penis during catheterization.

Insert the catheter slowly into the urethra until urine starts to flow. Hold onto the connector during the entire catheterization, to ensure the catheter stays in the urethra.



When urine stops flowing, pull the catheter out about 1-2 cm. If urine starts flowing again, wait until it stops. Then pull the catheter out 1-2 cm again. When your bladder is empty remove the catheter.

- 6) After use, the catheter can be pushed back into the packaging using a little force. Put the lid back on and discard.

**Symbols**



Do not use if package is damaged



Sterilized using Irradiation



Consult Instructions for use



Do not re-use



Use-by date



Batch code



Date of manufacture



Manufacturer: Coloplast A/S  
 Høttedam 1, 3050 Humlebaek, Denmark

To whom it may concern

06 January 2015  
DKAJL

Coloplast A/S  
Holtedam 1  
3050 Humlebæk  
Denmark  
Tel: +45 4911 1111  
www.coloplast.com  
CVR-nr. 69749917

Regarding question for Biocompatibility, K143182 SpeediCath Compact Male  
(Coloplast)

Anette Jansons Lauritzen  
BioSafety Specialist

EHS Development

Dir. tel. +45 4911 2369  
DKAJL@Coloplast.com

(b)(4)



Yours sincerely,

  
Anette Jansons Lauritzen