KIMTECH PURE*
A5 Sterile Apparel

DATA PACK

Kimberly-Clark PROFESSIONAL*

Exceptional Workplaces*

KIMTECH PURE* BRAND

DATA PACK - KIMTECH PURE* A5 Sterile Cleanroom Apparel
Contents

CLEAN-DON*, the Revolution in Aseptic Gowning.

KIMTECH PURE* A5 Sterile Cleanroom Coveralls.

The KIMTECH PURE* A5 Sterile Cleanroom Coveralls simplify aseptic gowning to save time and reduce the risk of contamination.

CLEAN-DON* blue line on the inside indicates correct place to grasp for aseptic gowning.

Telescope fold and snaps prevent legs and arms falling to the floor during gowning.

Vacuum Packed and double bagged for added sterility assurance.
Reduces space so more products fit into gowning area storage.

PERSONAL & PROCESS PROTECTION:

- Suitable for EU GMP ISO 5 Grade A cleanrooms
- Gamma Irradiated, Sterility Assurance Level 10^{-6}
- Low Lint fabric, Helmke Drum test Category I
- Bacterial Filtration Efficiency 96%
- Manufactured and Packed in ISO 5 cleanroom
- Vacuum packed for sterility assurance, saves space
- Certified PPE Cat III directive 89/686/EEC
- Type 6 limited chemical splash protection
- Type 5 particle protection
- Breathable barrier combines comfort and protection

DESIGN FEATURES:

- Unhooded coverall available in size S to 4XL
- Blue Indicator line to avoid touching outside
- Presented unzipped with inside-out fold
- Arms and legs telescope folded with snaps
- Waist and back panel elastics
- Elastic cuffs and thumb loops
- High strength, bound and triple stitched seams
- High performance SMS breathable barrier
- Individually vacuum packed and double bagged.
- 25 items per double case liner.

Applications:	EU GMP ISO 5 Grade A	Aseptic Processing	Parenteral Drug Manufacturing	Biotechnology	Pharmaceutical Compounding	Ophthalmic product manufacturing	Aseptic Hood work

CLEAN-DON*, the Revolution in Aseptic Gowning.

KIMTECH PURE* A5 Sterile Integrated Hood & Mask.

The KIMTECH PURE* A5 Sterile Integrated Hood & Mask simplifies aseptic gowning to save time and reduce the risk of contamination.

CLEAN-DON* blue line on the inside indicates correct place to grasp for aseptic gowning. Saves time and reduces contamination risk.

No gaps between hood and mask ensures exhaled air is filtered.
Elastics provide a comfortable, secure and universal fit.

Vacuum packed for added sterility assurance. Reduces space so more products fit into gowning area storage.

PERSONAL & PROCESS PROTECTION:

- Suitable for EU GMP ISO 5 Grade A cleanrooms
- Gamma Irradiated, Sterility Assurance Level 10^{-6}
- Low Lint fabric, Helmke Drum test Category I
- Bacterial Filtration Efficiency 96%
- Manufactured and Packed in ISO 5 cleanroom
- Vacuum packed for sterility assurance, saves space
- Certified PPE Cat III directive 89/686/EEC
- Type 6 Pb limited chemical splash protection
- Breathable barrier combines comfort and protection

DESIGN FEATURES:

- Integrated hood and mask
- Stretch fit elastics for universal size
- Blue Indicator line to avoid touching outside
- Pull down ties on back to assist gowning
- Presented inside-out fold to avoid contamination
- High strength, bound and triple stitched seams
- High performance SMS with cloth-like feel
- Individually vacuum packed
- 25 items per double-bag, 3 double bags per case

Applications:	EU GMP ISO 5 Grade A	Aseptic Processing	Parenteral Drug Manufacturing	Biotechnology	Pharmaceutical Compounding	Ophthalmic product manufacturing	Aseptic Hood work

CLEAN-DON*, the Revolution in Aseptic Gowning.

KIMTECH PURE* A5 Sterile Cleanroom Boot Covers.

The KIMTECH PURE* A5 Sterile Boot Covers improves worker safety and comfort, while reducing the risk of contamination.

New Version Ideal for wet applications. Wrap-around Vinyl foot is seamed above the floor line to reduce risk of liquid penetration and trip hazards.
Standard vinyl sole also available.

3 sizes for better safety and comfort. Better fit and comfort to improve worker safety by reducing risk of trip hazards.

Vacuum packed for added sterility assurance. Reduces space so more products fit into gowning area storage.

PROCESS PROTECTION:

- Suitable for EU GMP ISO 5 Grade A cleanrooms
- Gamma Irradiated, Sterility Assurance Level 10^{-6}
- Low Lint fabric, Helmke Drum test Category I
- Bacterial Filtration Efficiency 96%
- Manufactured and Packed in ISO 5 cleanroom
- Vacuum packed for sterility assurance, saves space
- CE 89/686/EEC Category I PPE – simple design
- Breathable barrier combines comfort and protection

DESIGN FEATURES:

- New Vinyl foot version available in 3 sizes.
- Standard Vinyl sole version available in 3 sizes.
- Elastic opening presented inside-out folded.
- Two extra-long ties.
- SMS material cloth-like feel keeps gloves in place
- High strength, bound and triple stitched seams
- Individually vacuum packed pairs
- 25 pairs per double-bag, 4 double bags per case

Applications:	EU GMP ISO 5 Grade A	Aseptic Processing	Parenteral Drug Manufacturing	Biotechnology	Pharmaceutical Compounding	Ophthalmic product manufacturing	Aseptic Hood work

CLEAN-DON*, the Revolution in Aseptic Gowning.

KIMTECH PURE* A5 Sterile Cleanroom Sleeves.

The KIMTECH PURE* A5 Sterile Cleanroom Sleeves simplify aseptic gowning to save time and reduce the risk of contamination.

CLEAN-DON* blue line on the inside indicates correct place to grasp for aseptic gowning.
Thumb-loops and material's cloth-like feel keep sleeves and gloves in place.

Telescoped fold makes aseptic gowning easier, preventing contact with the outside surface to reduce contamination risk.

Vacuum packed for added sterility assurance. Reduces space so more products fit into gowning area storage.

PROCESS PROTECTION:

- Suitable for EU GMP ISO 5 Grade A cleanrooms
- Gamma Irradiated, Sterility Assurance Level 10^{-6}
- Low Lint fabric, Helmke Drum test Category I
- Bacterial Filtration Efficiency 96%
- Manufactured and Packed in ISO 5 cleanroom
- Vacuum packed for sterility assurance, saves space
- CE 89/686/EEC Category I PPE – simple design
- Breathable barrier combines comfort and protection

DESIGN FEATURES:

- 45cm long sleeve protectors, pair packed.
- Blue Indicator line to avoid touching outside
- Telescope inside-out fold for easy gowning
- Elastic cuffs and thumb loops
- SMS material cloth-like feel keeps gloves in place
- High strength, bound and triple stitched seams
- Individually vacuum packed pairs
- 25 pairs per double-bag, 4 double bags per case

Applications:	EU GMP ISO 5 Grade A	Aseptic Processing	Parenteral Drug Manufacturing	Biotechnology	Pharmaceutical Compounding	Ophthalmic product manufacturing	Aseptic Hood work

KIMTECH PURE* A5 Sterile Cleanroom Apparel
Technical Data

Quality Standards

- Suitable for ISO 5 Grade A Sterile Cleanrooms
- Manufactured in ISO9001and ISO13485 certified facility
- Sterility Assurance Level 10^{-6} and Helmke Drum test Category I
- Sterilization in accordance with EN556-1, EN ISO11737-1,-2, EN ISO 11140-1

Fabric Tests	Test Method	Result
Particle shedding test (Helmke Drum)	IEST-RP-CC003.3	Category I
Bacterial Filtration Efficiency (3.0 µm) - SMS material in A5 fabric	ASTM F2100	96%
Bacterial Filtration Efficiency (3.0 µm) - Mask in iHAM	ASTM F2100	94%
Particle filtration Efficiency (0.5 µm) - SMS material A5 fabric	ASTM F2299	94%
Particle Filtration Efficiency (0.5 µm) - Mask in iHAM	ASTM F2299	93%
Abrasion resistance	EN 530 Method 2	Class 3 of 3
Flex cracking resistance	ISO 7854 Method B	Class 5 of 6
Trapezoidal tear resistance	ISO 9073-4	Class 2 of 3
Puncture resistance	EN 863	Class 1 of 3
Tensile strength	EN ISO 13934-1	Class 1 of 3
Resistance to ignition	EN 13274-4 Method 3	Pass
Seam strength	EN ISO 13935-2	Class 3 of 3

EN ISO 6350:2005 – Resistance of penetration by liquids/chemicals.	CAS number	Penetration Class	Penetration %	Repellency Class	Repellency %
1-butanol 100%	71-36-3	3	<1%	1	>80%
Ethanol 70%	64-17-5	3	<1%	2	>90%
Ethylene glycol 100%	107-21-1	3	<1%	2	>90%
Incidin Plus 100%	N/A	3	<1%	2	>90%
Isopropyl Alcohol 70%	67-63-0	2	<5%	1	>80%
Sekusept plus	N.A	3	<1%	2	>90%
Sodium Hydroxide 10%	1310-73-2	3	<1%	3	>95%
Sulphuric Acid 30%	7664-93-9	3	<1%	2	>90%

KIMTECH PURE* A5 Sterile Cleanroom Apparel

Description	Code.
Coveralls, 25 per Case	88800 (S), 88801 (M), 88802 (L), 88803 (XL), 88804 (2XL), 88805 (3XL), 88806 (4XL)
Boots Vinyl Foot, 100 pairs per Case	12922 (S), 88808 (Universal), 12920 (XL)
Boots Vinyl Sole, 100 pairs per Case	31683 (S), 31696 (Universal), 31697 (XL)

Description	Code.
Integrated Hood & Mask, 75 per Case	36072
Hood with Ties, 100 per Case	25797 / 88807
Sterile Sleeves, 100 pairs per Case	36077

KIMTECH PURE* A5 Sterile Cleanroom Apparel with CLEAN-DON* Technology

Gowning Procedure

BEFORE GOWNING

Step 1: (Pre-Entry) Don Hair Net and Shoe Covers after removing all jewelry and cosmetics.

Step 2: (Gowning) Wash hands and gown first pair of sterile gloves. Sanitize gloves after gowning each article if required.

Step 3: Apply mask and hood assuring a snug fit.

Step 4: **Open vacuumed-packed apparel.**
Tear at notched edge.

Step 5: **Grasp the blue line.**
Located on the inside middle back.

Step 6: **Gently unfold coverall utilizing blue indicator line.**
Arms and legs are pre-drawn and snapped in place. Garment is already folded inside-out and unzipped.

BEGIN GOWNING

Snaps allow gathered-up arms and legs to expand during gowning

Step 7: **Hold garment at waist**

Step 8: **Put one leg in and point toe through opening until snap releases**

Step 9: **Do the same with the other leg**

Step 10: **Insert one arm and extend until snap releases**

Step 11: **Do the same with the other arm**

Step 12: **Slip thumbs through thumb loops**

Final Step: **Cross legs and zip up coverall**

After A5 Sterile Cleanroom Apparel is Gowned:

Add boot covers

Complete gowning by adding goggles and a second pair of sterile gloves.

Printed in the USA. K01115 K2299-08-01 10/08

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KIMTECH PURE* A5 Integrated Hood and Mask Donning Technique

Step 1

Select your integrated hood and mask; inspect package for vacuum seal; tear along notches toward the product to open

Step 2

Pull out integrated hood and unfold to locate the blue signal indicator line

Step 3

Center your chin just above the blue line then roll over your forehead.

Step 4

Grab ties with both hands then extend arms out in a circular motion to position under armpits.

Step 5

Pull ties across chest and secure as needed

Step 6

Gently adjust front flap to comfortable position; pinch mask wire over bridge of nose to ensure proper fit.

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KIMTECH PURE* BRAND

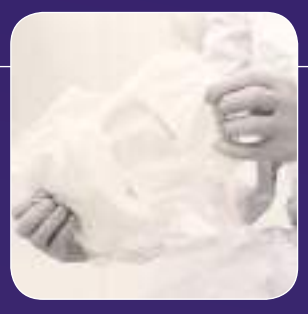
KIMTECH PURE* A5 Sterile Boot Cover with Grasp Ties Donning Technique

Step 1

Select your boot cover size; inspect package for vacuum seal; tear along notches toward the product to open; flex package to separate boot covers

Step 2

Pull out one boot cover by the cuff



Step 3

Grasp ties with one hand and make sure they don't touch the floor

Step 4

Open up boot cover; point toe towards opening and pull up over calf while holding the ties

Step 5

Hold up foot or rest on bench. Grasp ties at front of boot cover and wrap over cusp of shoe/boot; then wrap ties behind ankle and tie in front.

Step 6

Place donned boot on the clean side

Step 7

Pull the remaining boot cover out of package by the cuff and repeat Steps 3, 4 and 5. Proceed with final gowning steps

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KIMTECH PURE* A5 Sterile Cleanroom Apparel
Label Design

A5 Sterile Cleanroom Coveralls
88800 (S), 88801 (M), 88802 (L), 88803 (XL)
88804 (2XL), 88806 (3XL), 88806 (4XL)

A5 Sterile Cleanroom Sleeves
36072 – one size fits all

Case Label

Item Label

KIMTECH PURE* A5 Sterile Cleanroom Apparel
Label Design

A5 Sterile Cleanroom Hoods with ties
EU 88807(01) / US 25797(00)

A5 Sterile Integrated Hood & Mask
36072 – one size fits all

Case Label

Item Label

Please note:
From June 2013 production, 88807(01) will be dual coded to 25797 (US) / 88807 (EU).
This product is identical in design and specification.
Our European business will continue to refer to this product as 88807 in all price lists, literature and ordering systems.

KIMTECH PURE* A5 Sterile Cleanroom Apparel
Label Design

A5 Sterile Boot Covers with Vinyl Sole
12922 (S), 88808 (Universal), 12920 (XL)

A5 Sterile Boot Covers with Vinyl Foot
31683 (S), 31696 (Universal), 31697 (XL)

Case Label

Item Label

Certificate of Conformance
KIMTECH PURE* A5 Cleanroom Sterile Apparel

Product: **KIMTECH PURE* A5 Cleanroom Sterile Apparel**

Code	Description	Size	Packaging
88800	Coverall	S	25/case
88801	Coverall	M	25/case
88802	Coverall	L	25/case
88803	Coverall	XL	25/case
88804	Coverall	2XL	25/case
88805	Coverall	3XL	25/case
88806	Coverall	4XL	25/case
12917	Coverall	5XL	25/case
12914	Coverall	6XL	25/case
88807	Hood, no ties	One-Size	100/case
25797	Hood, with ties	One-Size	100/case
88808	Universal Boots	One-Size	100 pr/case
12922	Boots	S/M	100 pr/case
12920	Boots	XL/2XL	100 pr/case
31683	Boots, with edge vinyl	S/M	100 pr/case
31696	Boots, with edge vinyl	One-Size	100 pr/case
31697	Boots, with edge vinyl	XL/2XL	100 pr case

Lot number: XN213701X

This document certifies that the lots listed above conform to Kimberly-Clark's internal specifications for product quality. Kimberly-Clark uses a system of in-process and lot inspections to assure conformance to specifications.

Characteristic	Specification Target
Particle Count (Helmke Drum, IEST-RP-CC003.3)	Category I[1]
Sterility Assurance Level (ANSI/AAMI/ISO 11137)	10^{-6}

A Certificate of Irradiation is also available to assure that the product has received the specified radiation dosage.

Verified by:_____ Date: May 29, 2012

[1]Product is tested prior to sterilization
Customer Service: 800-255-6401

辐照证明书

CERTIFICATE OF IRRADIATION

深圳市金鹏源辐照技术有限公司
SHENZHEN JPY ION-TECH. CO., LTD.
地址（Add）：深圳市罗湖区布心工业路63号
No.58 Dongfeng Rd., Buxin, Luohu, Shenzhen 518019 China
电话(TEL)：+86(0)755 25177131, 25177197
传真(FAX)：+86(0)755 25916854,
邮政编码（P.C.）：518019
http://www.jpy.com.cn

证书编号：
Certificate No.: GM2012071502

分合同编号：
Sub-contract: GM12070127

B/SZJPY(B)-7515 AC/01

客户名称
Customer: Kimberly-Clark Professional

产品名称 Article description	包装规格(厘米) Carton Size(cm)	产品批号 Article Lot No.	数量(箱) Carton Qty(cs)	毛重(公斤) G.W(kgs)
Universal Boots:88808	50*30*37	XN218101X	*180*	1620
Sleeve:36077	50*30*37	XN218801X	*62*	334.8
Coverall: 88802	50*30*37	XN213701X	*32*	158.4
Coverall: 88805	50*30*42	XN213701X	*76*	845
Universal Boots:88808	50*30*37	XN218801X	*40*	360
以下空白				

这批产品已经过伽玛射线辐照。
THE PRODUCTS HAVE BEEN IRRADIATED BY GAMMARAY.

加工编号 Process Code No.	P1207153
辐照结束的日期 Irradiation lot finish date	2012-07-15
客户要求最低吸收剂量: Minimum specified dose: 32.5 kGy	最低剂量监测区吸收剂量: Minimum inspection area dose: 34.0 kGy
客户要求最高吸收剂量: Maximum specified dose: 50 kGy	最高剂量监测区吸收剂量: Maximum inspection area dose: 44.6 kGy
检验员: Inspector: 2012.7.15	深圳市金鹏源辐照技术有限公司 光明分公司 SHENZHEN JPY ION-TECH. CO., LTD. GUANGMING BRANCH
审核: Approved:	
日期: Date: 2012-7-15	

SteriPro Consulting

Protocol Number	Revision	Issue Date	Brief Description of Revision
797100277-P	0	April 12, 2010	[redacted]
[redacted]	1		
	2		

Protocol Title

VD-Max32.5 Radiation Validation for KIMTECH PURE* A5 Cleanroom Sterile Apparel

SteriPro Consultant: Zaxina Tumaitis

Sponsor Name and Address:	Sponsor Contact:
Kimberly-Clark 1400 Holcomb Bridge Road Roswell, GA 30076	Theresa McCoy

Prepared By
Zaxina Tumaitis
Consultant, SteriPro Consulting
Date

Reviewed By
Julie Arrage
Quality Assurance Manager, SteriPro Labs
Date

Approved By
Niki Fidopiastis
Director SteriPro Consulting
Date

Approved By
Theresa McCoy
Kimberly-Clark
April 14, 2010
Date

SteriPro will maintain copies of all Protocols, Final Reports, and supporting documentation for a retention period of five (5) years from the report issue date. After this period, SteriPro will contact the sponsor for disposition of these materials.

Confidential

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Tel 630 285 9121 • Fax 630 467 0960 • www.steripro.com

SteriPro
Consulting

Protocol Number	Revision	Issue Date	Brief Description of Revision
797100277-P	0	April 12 2010	[redacted]
[redacted]	1		
	2		

Protocol Title

VD-Max32.5 Radiation Validation for KIMTECH PURE* A5 Cleanroom Sterile Apparel

SteriPro Consultant: Zabrina Tumaitis

Sponsor Name and Address:
Kimberly-Clark
1400 Holcomb Bridge Road
Roswell, GA 30076

Sponsor Contact:
Theresa McCoy

Prepared By:
Zabrina Tumaitis
Consultant, SteriPro Consulting
Date

Reviewed By:
Julie Arriaga
Quality Assurance Manager, SteriPro Labs
Date

Approved By:
Niki Fidopiastis
Director, SteriPro Consulting
Digitally signed by Niki Fidopiastis
DN: cn=Niki Fidopiastis, o=Director of Consulting, ou=SteriPro, email=nfidopiastis@steripro.com, c=US
Date: 2010.04.14 07:34:02 -07'00'
Date

Approved By:
Theresa McCoy
Kimberly-Clark
Date

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SteriPro Consulting

Protocol Number	Revision	Issue Date	Brief Description of Revision
797100277-P	0	April 12, 2010	[redacted]
[redacted]	1		
	2		

Protocol Title

VD-Max32.5 Radiation Validation for KIMTECH PURE* A5 Cleanroom Sterile Apparel

SteriPro Consultant: Zabrina Tumaitis

Sponsor Name and Address:	Sponsor Contact
Kimberly-Clark 1400 Holcomb Bridge Road Roswell, GA 30076	Theresa McCoy

Prepared By: _____ Date: 12 Apr 10
Zabrina Tumaitis
Consultant, SteriPro Consulting

Reviewed By: _____ Date: 4-13-10
Julie Arriaga
Quality Assurance Manager, SteriPro Labs

Approved By: _____ Date: _____
Nik Fotopoulos
Director, SteriPro Consulting

Approved By: _____ Date: _____
Theresa McCoy
Kimberly-Clark

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1500 West Thorndale Avenue • Itasca, IL 60143
Tel 630.285.9121 • Fax 630.467.0980 • www.steripros.com

Terms and Conditions of Study

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Table of Contents

1. Scope

This study will be performed to establish a 32.5-kGy minimum dose and validate the effectiveness of Gamma Radiation sterilization of the KIMTECH PURE* A5 Cleanroom Sterile Apparel. Please refer to the Product Family Members Table below for all products included in this sterilization family. This protocol describes procedures for validation of radiation sterilization of medical products in accordance with AAMI TIR 33: *Sterilization of health care products – Radiation – Substantiation of a selected sterilization dose – Method VD-Max.*

Product Family Members
Description
Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralls - Size S
Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralls - Size M
Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralls - Size L
Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralls - Size XL
Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralls - Size 2XL
Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralls - Size 3XL
Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralls - Size 4XL
Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralls - Size 5XL
Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralls - Size 6XL
Kimtech Pure* A5 Cleanroom Sterile Apparel - Hoods - One size fits all
Kimtech Pure* A5 Cleanroom Sterile Apparel - Boots – Size S/M
Kimtech Pure* A5 Cleanroom Sterile Apparel - Boots – Size L
Kimtech Pure* A5 Cleanroom Sterile Apparel - Boots – XL/2XL

2. Objectives

2.1. Preliminary bioburden data has determined the Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralls - Size 6XL as the Dose Setting Device for this sterilization family

2.2 The Dose Setting Device for the product family will be the test sample for this validation. Pre-sterilization bioburden level will be determined to establish the appropriate verification dose.

2.3 Recommendation for a routine minimum sterilization dose will be based on evaluation of microbial survivors following exposure of products to the verification dose. The minimum dose of 32.5 kGy will be designed to provide a Sterility Assurance Level (SAL) of 10^{-6} or not more than one non-sterile unit for each one million units sterilized at that dose level.

2.4. This study is intended to support release of products for which exposure to the minimum required dose can be demonstrated by the use of calibrated dosimeters and without post-exposure sterility testing of each lot.

3. Rationale

3.1 The VD-Max validation is utilized to determine the minimum effective processing dose for radiation sterilization. The validation is based on the concept that the product bioburden for the overall average or a single lot average (if greater than twice the overall average) bioburden will be less than 100,000 colony forming units.

3.2 The VD-Max procedure analyzes the number and resistance of the bioburden on the product. Three independent lots of product are tested for bioburden levels, and the bioburden recovery efficiency (percent recovery) is determined. The bioburden recovery efficiency and the sample item portion (percent of unit tested) are used to calculate the theoretical device bioburden on each test unit. The final bioburden estimate is used to determine the verification dose from the radiation dose tables specified in AAMI TIR 33.

3.3. The verification dose (sub-lethal) provides a SAL of 10^{-1}. A verification experiment must be performed to verify that the product bioburden resistance is less than or equal to the standard distribution of resistances used in the AAMI radiation guidelines.

3.4. Following completion of the study, a final report shall be generated by SteriPro, which shall be signed and approved by designated individuals from SteriPro, and Kimberly-Clark. This report shall be submitted to Kimberly-Clark and SteriPro will retain a copy as specified in the SteriPro procedure for record retention.

4. Terms and Definitions

Refer to ANSI/AAMI/ISO 11137:2006, AAMI TIR 33, and ANSI/AAMI/ISO 11737:2006 for definitions of terminology.

5. Responsibilities

5.1 Contract Irradiator
Sterigenics, Corona or Charlotte will be responsible for all equipment, process qualification, dosimeter calibration, and all documentation involving the ExCell irradiator's validation. A certificate of processing will be provided for the product in this study. All other Sterigenics records that are specific to this study will be available to the sponsor upon request or audit.

5.2. Contract Laboratory
SteriPro Labs, Itasca will perform the necessary microbiological testing for this validation and will provide all necessary documentation for the Final Report. DNV Certification, certificate numbers 2005-OSL-AQ-7662 and 2005-OSL-AQ-0212 certify SteriPro Labs to ISO 9001 and ISO 13485.

6. Product Specifications

6.1. Product Sample Amounts
Forty-eight (48) finished, routine product samples will be submitted in standard, final packaging format for all testing. These units shall be pulled after all steps of production except sterilization and be produced under current good manufacturing practice conditions. From the 48 product samples, there shall be three independent lots of ten samples each for bioburden determination. The 18 remaining samples may come from one or more production lots.

6.2. Sample Item Portion (SIP)
The SIP used for all testing will be 0.10. The SIP that will be tested as the test sample will consist of different parts of the coverall for a total SIP of 0.10.

6.3. Sample Preparation
Additional sample prep is needed prior to sterilization in order to facilitate testing.

7. Bioburden Study Method

7.1. Recovery Determination

7.1.1. Efficiency of Recovery Factor (ERF) will be determined using a specific bioburden recovery test procedure, which will be performed on a minimum of five samples taken from one or more production lots. This test is performed to determine the percentage of microorganisms that can be recovered from a product.

7.1.2. Averaging the recovery obtained from the samples tested will derive the recovery factor. The bioburden test results for each lot will be adjusted by applying the ERF, in order to obtain a theoretical bioburden estimate. This theoretical bioburden estimate is a more accurate representation of the actual number of microorganisms on the product.

7.2. Recovery Test Method
The bioburden recovery test method for the product will be performed using the repetitive extraction method or inoculated recovery method. The extraction method will be the same as the method used for the bioburden determination. This testing will be conducted using test parameters outlined in ANSI/AAMI/ISO 11737-1.

7.3. Bioburden Determination
Ten samples each from three independent lots will be tested for bioburden using a specific test procedure. Each lot will have the results reported in colony forming units (CFU), with the ERF applied. The bioburden test will include aerobic bacteria and fungal enumerations.

7.4. Bioburden Test Method
The bioburden test method will be performed by immersion of the SIP. This testing will be conducted using test parameters defined in ANSI/AAMI/ISO 11737-1.

8. Verification Study Method

8.1. Verification Dose Determination

8.1.1. A verification dose will be determined using the tables specified in AAMI TIR 33. The verification dose determination will be based on the final bioburden estimate for the product.

8.1.2. Thirteen packaged verification samples will be sent to Sterigenics for irradiation at the calculated verification dose. The actual dose delivered will be measured and documented by Sterigenics. Sterigenics will send the samples directly to the contract laboratory after the verification dose has been performed.

8.2. Verification Dose Range
If the maximum delivered dose exceeds the verification dose by more than 10%, the verification dose shall be repeated. If the maximum and minimum delivered dose is less than 90% of the verification dose, the verification dose may be repeated. If the delivered dose is less than 90% of the verification dose, and on the tests of sterility acceptable results are obtained, the verification experiment need not be repeated.

8.3. Test of Sterility
The test of sterility requires ten of the verification dose samples. The results will be reported as number of samples with growth and/or the number of samples with negative growth for the ten verification dose samples.

8.4. Test of Sterility Method
The test method will be performed by direct immersion. The test will be conducted using test parameters outlined in AAMI TIR 33 and ANSI/AAMI/ISO 11737-2.

8.5. Bacteriostasis/Fungistasis Determination
The bacteriostasis/fungistasis test requires three of the verification dose samples. This test is a validation of the test of sterility. This test will be conducted to verify that no bacteriostatic and fungistatic activity, which might compromise the sensitivity of the sterility test method, was exhibited by the samples, or formed by the verification dose exposure. The test results will be reported as a pass or fail.

8.6. Bacteriostasis/Fungistasis Test Method
The testing method will be the same as the method used for the test of sterility. The test will be performed using parameters outlined in the current USP.

9. Acceptance Criteria

Interpretation of results will be acceptable or unacceptable, as defined in AAMI TIR 33

9.1. Verification is accepted if there are no more than one positive sterility test units out of the ten tested.

9.2. If two positives occur, perform another sterility test on ten additional units that have been irradiated at the same verification dose determined above. Upon completion of the second sterility test, add the number of positives from the two tests together. If the total number is two positives, verification is accepted.

9.3. If three or more positives occur, verification is not accepted. If the positive sterility units cannot be attributed to incorrect testing or dosing, an alternative dose determination method should be used unless the cause of the failure can be identified and corrected.

9.4. Bacteriostasis/Fungistasis test passes.

10. Routine Sterilization

10.1. The routine sterilization dose is based on the acceptable results as outlined in Section 9 of this protocol. The 32.5-kGy minimum sterilization dose is considered valid for achieving a 10^{-6} SAL for the product listed.

10.2. With completion and acceptance of this validation study, subsequent batches of the product may be sterilized at a minimum dose of 32.5-kGy and released for use based only on the dosimeters indicating that the minimum SAL of 10^{-6} dose has been delivered to the product.

10.3. Dose audits must be performed according to an established schedule, as indicated in ANSI/AAMI/ISO 11137-1

11. References

11.1 ANSI/AAMI/ISO 11737-1:2006, Sterilization of health care products – Microbiological methods – Part 1: Determination of the population of microorganisms on product

11.2 ANSI/AAMI/ISO 11737-2:2009, Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

11.3. ANSI/AAMI/ISO 11137-1:2006, Sterilization of health care products – Radiation – Part 1 Requirements for development, validation, and routine control of a sterilization process for medical devices

11.4. ANSI/AAMI/ISO 11137-2:2006, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose

11.5. AAMI TIR 33:2005, Sterilization of health care products – Radiation – Substantiation of a selected sterilization dose – Method VD-Max

11.6. USP/NF U.S. Pharmacopoeia (current version)

SteriPro Labs

BIOBURDEN TEST REPORT

Procedure Reference: LB-MIC-004

SteriPro® Labs WO#: 401711-MIC-004-I

Date Received: 03/29/10

Customer:	Kimberly-Clark 1400 Holcomb Bridge Road Roswell, GA 30076	Product: Cat / Part #: Lot #:	KIMTECH PURE* A5 Cleanroom Sterile Apparel- Boots 2XL 12920 AR007702X

Customer Specification Sheet# / Rev #: I-004-411/ Rev. 2 Efficiency Recovery Factor (ERF): N/A

Test Media	Manufacturer	Lot No.	Exp. Date
Tryptic Soy Agar (TSA):	Biomereux	ITMFR432	07/14/10
Sabouraud Dextrose Agar (SDA):	SteriPro	IT01/03132	03/17/11
Phosphate Buffered Saline (PBS):	SteriPro	IT02303143	03/23/11

Sample Preparation: Each sample was immersed.

Total Rinse Volume: 200mL Volume Extracted per Organism Type: 40mL

Enumeration Method: ___ Pour Plate X Filtration ___ Surface

TSA Incubation Temperature: 30-35°C SDA Incubation Temperature: 20-25°C

Date Extracted/Incubated: 03/30/10 Date TSA Enumerated: 04/02/10 Date SDA Enumerated: 04/05/10

TEST RESULTS (Colony Forming Units (CFU) per Device):

Sample ID	Aerobes (TSA)	Fungi-Yeast/Mold (SDA)
1	120	<5
2	120	<5
3	130	<5
4	115	<5
5	135	10
6	235	5
7	150	10
8	135	5
9	175	5
10	125	<5
Total Average Bioburden/Device (calculated with ERF, if applicable)	144.0	5.0

Control Results: TSA 0 SDA 0 PBS 0

Comments:

Prepared By: _____ Date: 4/7/10

Reviewed By: _____ Date: 4/7/10

BIOBURDEN TEST REPORT

Procedure Reference: LB-MIC-004

SteriPro Labs

SteriPro® Labs WO#: 401710-MIC-004-I

Date Received: 03/29/10

Customer:	Kimberly-Clark 1400 Holcomb Bridge Road Roswell, GA 30076	Product: Cat / Part #: Lot #:	KIMTECH PURE* A5 Cleanroom Sterile Apparel- Hood 88507 AR007502X

Customer Specification Sheet# / Rev #: I-004-411/ Rev. 2 Efficiency Recovery Factor (ERF): N/A

Test Media	Manufacturer	Lot No.	Exp. Date
Tryptic Soy Agar (TSA):	Biomerieux	ITMFR432	07/14/10
Sabouraud Dextrose Agar (SDA):	SteriPro	IT01703132	03/17/11
Phosphate Buffered Saline (PBS):	SteriPro	IT02303143	03/23/11

Sample Preparation: Each sample was immersed

Total Rinse Volume: 200mL Volume Extracted per Organism Type: 40mL

Enumeration Method: _ Pour Plate X Filtration _ Surface

TSA Incubation Temperature: 30-35°C SDA Incubation Temperature: 20-25°C

Date Extracted/Incubated: 03/30/10 Date TSA Enumerated: 04/02/10 Date SDA Enumerated: 04/05/10

TEST RESULTS (Colony Forming Units (CFU) per Device):

Sample ID	Aerobes (TSA)	Fungi-Yeast/Mold (SDA)
1	175	<5
2	210	30
3	200	5
4	180	5
5	175	5
6	200	<5
7	215	10
8	190	5
9	270	15
10	125	10
Total Average Bioburden/Device (calculated with ERF if applicable)	**194.0**	**9.5**

Control Results: TSA 0 SDA 0 PBS 0

Comments:

Prepared By: _____ Date: 4/7/10

Reviewed By: _____ Date: 4/7/10

BIOBURDEN EXHAUSTIVE RECOVERY VALIDATION TEST REPORT

Procedure Reference: LB-MIC-004

SteriPro® Labs WO#: 401712-MIC-004-I

Date Received: 03/29/10

Customer:	Kimberly-Clark 1400 Holcomb Bridge Road Roswell, GA 30076	Product: Cat / Part #: Lot #:	KIMTECH PURE* A5 Cleanroom Sterile Apparel-coveralls-6XL 12914 AR007602A

Customer Specification Sheet# / Rev #: I-004-411/ Rev 2 Efficiency Recovery Factor (ERF): N/A

Test Media	Manufacturer	Lot No.	Exp. Date
Tryptic Soy Agar (TSA):	Biomerieux	ITMFR437	07/29/10
Sabouraud Dextrose Agar (SDA):	SteriPro	IT01703132	09/17/11
Phosphate Buffered Saline (PBS):	SteriPro	IT02303143	03/23/11

Sample Preparation: For each sample, an SIP of 10% was cut and immersed in PBS

Total Rinse Volume: 200mL Volume Extracted per Organism Type: 40mL

Enumeration Method: ____ Pour Plate X Filtration ____ Surface

TSA Incubation Temperature: 30-35°C SDA Incubation Temperature: 20-25°C

Date Extracted/Incubated: 04/01/10 Date TSA Enumerated: 04/05/10 Date SDA Enumerated: 04/06/10

See Following Page(s) for Repetitive Wash Results

Calculated Efficiency Recovery Factor (ERF): 0.27

Comments:

Prepared By: _____ Date: 4/12/10

Reviewed By: _____ Date: 4/12/10

BIOBURDEN EXHAUSTIVE RECOVERY VALIDATION TEST REPORT

Procedure Reference: LB-MIC-004

SteriPro® Labs WO#: 401712-MIC-004-I

TEST RESULTS (Colony Forming Units (CFU) per Device):

FIRST WASH

Sample ID	Aerobes (TSA)	Fungi-Yeast/Mold (SDA)
1	1850	50
2	2200	150
3	1050	50
4	1650	<50
5	1200	50
Total Average Bioburden/Device	**1630**	**70**

SECOND WASH

Sample ID	Aerobes (TSA)	Fungi-Yeast/Mold (SDA)
1	2300	50
2	1800	50
3	2850	50
4	2650	<50
5	1750	<50
Total Average Bioburden/Device	**2270**	60

THIRD WASH

Sample ID	Aerobes (TSA)	Fungi-Yeast/Mold (SDA)
1	2900	50
2	2150	100
3	2000	100
4	2550	50
5	1700	50
Total Average Bioburden/Device	**2300**	70

Control Results: TSA 0 SDA 0 PBS 0

SteriPro Labs

BIOBURDEN TEST REPORT

Procedure Reference: LB-MIC-004

SteriPro® Labs WO#: 401709-MIC-004-I

Date Received: 03/29/10

Customer:	Kimberly-Clark 1400 Holcomb Bridge Road Roswell, GA 30076	**Product:**	KIMTECH PURE* A5 Cleanroom Sterile Apparel- Coveralls-8XL
		Cat / Part #:	12914
		Lot #:	AR007602A

Customer Specification Sheet# / Rev #: I-004-411/ Rev. 2 **Efficiency Recovery Factor (ERF):** 0.27

Test Media	Manufacturer	Lot No.	Exp. Date
Tryptic Soy Agar (TSA):	Biomerieux	ITMFR432	07/14/10
Sabouraud Dextrose Agar (SDA):	SteriPro	IT01703132	03/17/11
Phosphate Buffered Saline (PBS):	SteriPro	IT02303143	03/23/11

Sample Preparation: An SIP of 10% of sample was cut and immersed.

Total Rinse Volume: 200mL **Volume Extracted per Organism Type:** 40mL

Enumeration Method: _ Pour Plate X Filtration _ Surface

TSA Incubation Temperature: 30-35°C **SDA Incubation Temperature:** 20-25°C

Date Extracted/Incubated: 03/30/10 **Date TSA Enumerated:** 04/02/10 **Date SDA Enumerated:** 04/05/10

TEST RESULTS (Colony Forming Units (CFU) per Device):

Sample ID	Aerobes (TSA)	Fungi-Yeast/Mold (SDA)
1	1750	<50
2	1800	200
3	1850	50
4	3050	50
5	2250	150
6	1700	200
7	2950	100
8	2000	150
9	2750	200
10	1950	200
Total Average Bioburden/Device (calculated with ERF, if applicable)	**8166.7**	**500.0**

Control Results: TSA 0 SDA 0 PBS 0

Comments:

Prepared By: _____ **Date:** 4/6/10

Reviewed By: _____ **Date:** 4/7/10

BIOBURDEN TEST REPORT

Procedure Reference: LB-MIC-004

SteriPro® Labs WO#: 407027-MIC-004-I

Date Received: 04/07/10

Customer:	Kimberly-Clark 1400 Holcomb Bridge Road Roswell, GA 30076	Product: Cat / Part #: Lot #:	KIMTECH PURE* A5 Cleanroom Sterile Apparel-Coveralls-6XL 12914 AR010402B

Customer Specification Sheet# / Rev #: I-004-411/ Rev. 3 Efficiency Recovery Factor (ERF): 0.27

Test Media	Manufacturer	Lot No.	Exp. Date
Tryptic Soy Agar (TSA):	Biomerieux	ITMFR437	07/29/10
Sabouraud Dextrose Agar (SDA):	SteriPro	IT01703132	03/17/11
Phosphate Buffered Saline (PBS):	SteriPro	IT00104165	04/01/11

Sample Preparation: Each SIP of 10% was cut and immersed in PBS.

Total Rinse Volume: 200mL Volume Extracted per Organism Type: 40mL

Enumeration Method: ___ Pour Plate X Filtration ___ Surface

TSA Incubation Temperature: 30-35°C SDA Incubation Temperature: 20-25°C

Date Extracted/Incubated: 04/08/10 Date TSA Enumerated: 04/12/10 Date SDA Enumerated: 04/13/10

TEST RESULTS (Colony Forming Units (CFU) per Device):

Sample ID	Aerobes (TSA)	Fungi-Yeast/Mold (SDA)
1	2300	150
2	3200	200
3	2350	100
4	2850	<50
5	5250	<50
6	4500	100
7	3400	50
8	2000	<50
9	3250	50
10	1850	50
Total Average Bioburden/Device (calculated with ERF if applicable)	11463.0	314.8

Control Results: TSA 0 SDA 0 PBS 0

Comments:

Prepared By: _____ Date: 4/14/10

Reviewed By: _____ Date: 4/14/10

SteriPro

BIOBURDEN TEST REPORT

Procedure Reference: LB-MIC-004

SteriPro® Labs WO#: 407026-MIC-004-I

Date Received: 04/07/10

Customer:	Kimberly-Clark 1400 Holcomb Bridge Road Roswell, GA 30076	Product: Cat / Part #: Lot #:	KIMTECH PURE* A5 Cleanroom Sterile Apparel-Coveralls-6XL 12914 AR010402C

Customer Specification Sheet# / Rev #: I-004-411/ Rev. 3 Efficiency Recovery Factor (ERF): 0.27

Test Media	Manufacturer	Lot No.	Exp. Date
Tryptic Soy Agar (TSA):	Biomerieux	ITMFR437	07/29/10
Sabouraud Dextrose Agar (SDA):	SteriPro	IT01703132	03/17/11
Phosphate Buffered Saline (PBS):	SteriPro	IT00104165	04/01/11

Sample Preparation: Each SIP of 10% was cut and immersed in PBS.

Total Rinse Volume: 200mL Volume Extracted per Organism Type: 40mL

Enumeration Method: ____ Pour Plate X Filtration ____ Surface

TSA Incubation Temperature: 30-35°C SDA Incubation Temperature: 20-25°C

Date Extracted/Incubated: 04/08/10 Date TSA Enumerated: 04/12/10 Date SDA Enumerated: 04/13/10

TEST RESULTS (Colony Forming Units (CFU) per Device):

Sample ID	Aerobes (TSA)	Fungi-Yeast/Mold (SDA)
1	4250	<50
2	4800	100
3	2050	<50
4	2150	100
5	3900	150
6	3100	150
7	1800	<50
8	2250	50
9	2700	50
10	2750	100
Total Average Bioburden/Device (calculated with ERF, if applicable)	**11018.5**	**314.8**

Control Results: TSA 0 SDA 0 PBS 0

Comments:

Prepared By: _____ Date: 4/14/10

Reviewed By: _____ Date: 4/14/10

SteriPro Consulting

Dose Calculation for Kimberly-Clark
KIMTECH PURE* A5 Cleanroom Sterile Apparel

Based on the Total Recoverable Aerobic and Fungi Bioburden results from three independent lots of the KIMTECH PURE* A5 Cleanroom Sterile Apparel, the theoretical overall average taken from the three lots was selected to calculate the subprocess Verification dose. The Recovery Factor was determined to be 0.27.

Per AAMI TIR33: Method VD-Max30 guidelines, the Sub-process Verification dose is based on the overall average bioburden from three lots, unless one of the averages is two or more times greater than that of that overall average. The verification dose was derived from the theoretical bioburden average of the three lots. The theoretical lot averages are as follows.

Lot Number	Total Bioburden (Aerobic and Fungal) As colony forming units (cfu) per device
AR0076O2A	8666.7 cfu/device
AR010402B	11777.8 cfu/device
AR0104C2C	11333.3 cfu/device

The overall average bioburden for the three lots, including the recovery factor is 10592.6 cfu per device. Based on 10592.6 cfu per device, and utilizing the SIP verification dose calculation the verification dose was determined directly from Table A.7 of the AAMI TIR33 guidance. The verification dose for the device is **9.9 kGy**

In accordance with the AAMI TIR33, Method VD-Max30 guidelines, ten units of product should be sampled from a single production lot and irradiated at the verification dose of 9.9 kGy ± 10%. After irradiation the samples will be sent to SteriPro Labs to be placed on test of sterility.

If these ten units, which will have been irradiated at 9.9 kGy, meet the criteria set forth in the AAMI TIR33: Method VD-Max30 guidelines (no more than one positive per ten units), then the minimum sterilization dose from a sterility assurance level would be 30.0 kGy.

Best Regards,

Zabrina Tumanis
Consultant, SteriPro Consulting

Sterigenics.

Certificate of Processing

STERIGENICS 344 Bonnie Circle Corona CA 92880
TEL 951 340-0700 FAX www.sterigenics.com

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R60001

04/19/10 16:06:51 GMT
Page - 1 of 1

Customer Name: SoerPro Consulting
P.O.# 12334270 / KIMBERLY CLARK

Processing Facility: Corona

Work Order # 413952
Sales Order # 383808

K_STERIPRO_18

Irradiation Date/Time: 04/18/10 17:03:00 GMT
Irradiation Cell: EXCELL

SO Line #	Qty	UOM	Customer Item Number / Customer Item Description	Customer Lot Number / Customer Load Number
101.00	1	CA	X_CANYON_STERIPRO_18	AR3078020 COVERALLS - 6XL
	1	CA	Total	

Quality Test Summary

Opt	Quality Test Description	Result	Pass/Fail	User	Date	Time
450.00	Minimum Dose	9.4 kGy	Pass	JGARCIA Jose Garcia	04/19/10	01:38:28 GMT
		Reason Code Test				
450.00	Maximum Dose	10.2 kGy	Pass	JGARCIA Jose Garcia	04/19/10	01:38:44 GMT
		Reason Code Test				

Sterigenics certifies that the materials listed above (or described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry systems employed.

Electronically Signed By: Amanda Posada
Work Order Completion

Date: 04/19/10 16:00:47 GMT

STERILITY VALIDATION (B&F) TEST REPORT

Procedure Reference: LB-MIC-027

SteriPro® Labs WO#: 415045-MIC-027-I **Page** 1 **of** 1

Date Received: 04/20/10 **Date On-Test:** 04/21/10 **Date Off-Test:** 04/26/10

Customer:	Kimberly Clark 1400 Holcomb Bridge Road Roswell, GA 30076	**Product:**	KIMTECH PURE* A5 Cleanroom Sterile Apparel- Coveralls -6XL
		Cat / Part #:	12914
		Lot #:	AR007602B
		Load #:	N/A
		Sterilization Run:	412952
		Date Sterilized:	04/19/10

Test Media	Manufacturer	Volume	Lot No.	Exp. Date
			IT01204165	04/12/11
TSB	SteriPro	3000mL	IT01904195	04/19/11

Product Sterility Customer Specification Sheet# / Revision: I-036-797/Rev. 0

Test Method:
Immersion of SIP

Test Results: X **PASS** _____ **FAIL**

ORGANISM	TSB	
	Control	Sample
Bacillus subtilis (ATCC #6633)	+	+
Candida albicans (ATCC #10231)	+	+
Aspergillus niger (ATCC #16404)	+	+

Comments:
N/A

Prepared By: _____ **Date:** 4/27/10

Reviewed By: _____ **Date:** 4/27/10

SteriPro Labs

PRODUCT STERILITY TEST REPORT

Procedure Reference: LB-MIC-036

SteriPro® Labs WO#: 415039-MIC-036-I **Page** 1 **of** 1

Date Received: 04/20/10 **Date On-Test:** 04/21/10 **Date Off-Test:** 05/05/10

Customer:	Kimberly –Clark 1400 Holcomb Bridge Road Roswell, GA 30076	**Product:**	KIMTECH PURE* A5 Cleanroom Sterile Appareal-Coveralls-6XL
		Cat / Part #:	12914
		Lot #:	AR007602B
		Load #:	AR007602B
		Sterilization Run:	412952
		Date Sterilized:	04/19/10

Test Media	Manufacturer	Volume	Lot No.	Exp. Date
Tryptic Soy Broth (TSB)	SteriPro Labs	3000mL	IT01204165	04/12/11

Number of Samples: 10

Customer Specification Sheet# / Revision #: I-036-797/ Rev 0

Test Method:
Immersion of SIP.

Test Results:

TSB:	X	**No Growth**		**Growth**
Open Control:	X	**No Growth**		**Growth**

Results Meet Criteria: X **YES** **NO**

Attachments Included: N/A

Comments: N/A

Prepared By: Alix Carter **Date:** 5/5/10

Reviewed By: Catherine Beat **Date:** 5/6/10

Dose setting Report

Kimberly-Clark Corporation

1400 Holcomb Bridge Road, Roswell, Georgia

The following sample(s) was/were submitted and identified on behalf of the applicant as:

Kimtech Pure A5 Sterile Integrated Hood and Mask

Date of Sample Receipt	2013/03/04
Lab Test ID	13-033A
Date on Test	2013/03/04
Test Item	Dose Setting
Test Method	ISO 11137-2-2012: Method 1

Signature

Trudy Shu 2013-04-01
Edited by Date

Jake Song 2013-04-01
Reviewed by Date

Sergio Xu 2013-04-01
Approved by Date

Sherman McCoy 2013-04-01
Kimberly-Clark Professional

Revision

0	2013/04/01	First edition
Revision No.	**Date**	**Revision Description**

- **Tested sample description**

Sample information	
Sample name	Kimtech Pure A5 Sterile Integrated Hood and Mask
Product code	36072
Lot*	First batch, second batch, third batch
Number of Sample	138 samples
SIP	1.0

- **Sample photo**

- **Test results**

✧ **Bioburden validation (Inoculation)**

Bioburden validation test results(Sample Lot: Second batch)					
Sample ID	Counted	PF	Recovered per sample(CFU)	Confirmed Inoculation level(CFU)	ERF
1	14	2.0	28	52/48	0.56
2	13		26		0.52
3	14		28		0.56
4	13		26		0.52
5	10		20		0.40
Average	12.8	NA	25.6	50	0.51
C.F (Correction Factor)		2.0			

✧ **Bioburden test**

Bioburden Test Result (Sample Lot: First batch)						
ID	CFU count		CFU Counted	P.F	C.F	CFU/ SIP sample
	Aerobes	Fungi				
1	164	87	251	4	2.0	2008
2	135	22	157			1256
3	221	87	308			2464
4	156	112	268			2144
5	142	47	189			1512
6	348	80	428			3424
7	98	45	143			1144
8	125	8	133			1064
9	147	48	195			1560
10	127	64	191			1528
control	0	0	N/A	N/A	N/A	N/A
SIP Average	1810.4 CFU/SIP sample					
Batch 1 Average	**1810.4 CFU/Device**					
Bioburden Test Result (Sample Lot: Second batch)						
ID	CFU count		CFU Counted	P.F	C.F	CFU/ SIP sample
	Aerobes	Fungi				
1	259	67	326	4	2.0	2608
2	91	40	131			1048
3	301	68	369			2952
4	424	42	466			3728
5	147	52	199			1592
6	324	124	448			3584
7	235	68	303			2424
8	184	10	194			1552

9	242	62	304			2432
10	187	74	261			2088
control	0	0	N/A	N/A	N/A	N/A
SIP Average	2400.8 CFU/SIP sample					
Batch 2 Average	**2400.8 CFU/Device**					
Bioburden Test Result (Sample Lot: Third batch)						
ID	CFU count		CFU Counted	P.F	C.F	CFU/ SIP sample
	Aerobes	Fungi				
1	145	56	201	4	2.0	1608
2	149	10	159			1272
3	260	56	316			2528
4	145	48	193			1544
5	140	34	174			1392
6	256	52	308			2464
7	88	79	167			1336
8	98	25	123			984
9	231	60	291			2328
10	296	84	380			3040
control	0	0	N/A	N/A	N/A	N/A
SIP Average	1849.6 CFU/SIP sample					
Batch 3 Average	**1849.6 CFU/Device**					

✧ **Establishing sterilization dose**

Establishing sterilization dose			
Overall average bioburden(SIP)	Verification dose (SIP sample)	Overall average bioburden (Device)	Sterilization dose (10^{-6})
2020.3 CFU	12.0 kGy	2020.3 CFU	26.1 kGy

Note: Overall average bioburden= (batch1+batch2+batch3)/3= (1810.4+2400.8+1849.6)/3= 2020.3 CFU/device

✧ **Irradiation of verification dose**

Verification dose is irradiated on 100 samples (Lot: XN306301X) within the ±10% of target dose 12.0 kGy. Detail information refers to **Certificate of Irradiation for Test Sample** from **Sterigenics Shanghai E-Beam Co., Ltd (PO20130314128391)**.

✧ **Sterility test validation (Bacteriostasis & Fungistasis Test)**

Sterility Test Validation (B/F) Result			
Culture	*Bacillus subtilis* ATCC 6633	*Candida albicans* ATCC10231	*Aspergillus brasiliensis* ATCC16404
Test Sample	Positive	Positive	Positive
Inoculated Control	Positive	Positive	Positive
Inoculum Level(CFU)	31	39	30
Conclusion	The products of **Kimtech Pure A5 Sterile Integrated Hood and Mask (Code: 36072)** do **not exist** bacteriostatic and fungistatic properties, or such properties have been **eliminated** through the test.		

✧ **Sterility test**

Sterility Test Result	
SIP	1.0
Sample number	100
Type of Media	TSB
Media Volume	800mL
Incubation Period	14 days
Incubation Temperature	28°C - 32°C
Results	1 Positive

- **Conclusion**

From validation results show, the product of **Kimtech Pure A5 Sterile Integrated Hood and Mask (Code: 36072)** **PASS** the dose setting by using Method 1 according to ISO 11137-2. A sterility assurance level (SAL) of 10^{-6} is confirmed when irradiating the product by a sterilization dose of 26.1 kGy for routine production.

- **References**

✧ ISO 11737-1:2006 Sterilization of health care products - Microbiological methods - Part 1: Determination of the population of microorganisms on product

✧ ISO 11737-2:2009 Sterilization of medical devices--Microbiological methods---Part2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

- ISO 11137-2:2006 Sterilization of health care products---Radiation---Part 2: Establishing the sterilization dose
- Sterigenics internal Work Instruction SHEB-WI-LB-MIC-003
- Sterigenics internal Work Instruction SHEB-WI-LB-MIC-016

Remarks

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- The test report is invalid if altered.
- Please contact testing laboratory within 15 days after receiving the test report if any objection to the report, otherwise it will not be accepted.
- The test report is only responsible for the sample provided by customer.
- The test report cannot be used for any commercial purpose unless approved by testing laboratory.
- Tested by SteriPro laboratory, Sterigenics Shanghai E-Beam Ltd.
  No.588 ChuanTu Road, Chuansha. Pudong, Shanghai. China. 201202.
  Tel(86-21) 58594680 Fax(86-21)58599310

==========End of report==========

Dose setting Report

Kimberly-Clark Corporation

1400 Holcomb Bridge Road, Roswell, Georgia

The following sample(s) was/were submitted and identified on behalf of the applicant as:

Kimtech Pure A5 Sterile Sleeves

Date of Sample Receipt	2013/03/04
Lab Test ID	13-033A
Date on Test	2013/03/04
Test Item	Dose Setting
Test Method	ISO 11137-2-2012: Method 1

Signature

Judy Zhu 2013-04-01
Edited by **Date**

Luke Song 2013-04-01
Reviewed by **Date**

Simon Yu 2013-04-01
Approved by **Date**

Theresa McCoy 2013-04-01
Kimberly-Clark Professional

Revision

0	2013/04/01	First edition
Revision No.	**Date**	**Revision Description**

- **Tested sample description**

Sample information	
Sample name	Kimtech Pure A5 Sterile Sleeves
Product code	36077
Lot#	First batch, second batch, third batch
Number of Sample	138samples
SIP	1.0

- **Sample photo**

- **Test results**

✧ **Bioburden validation (Inoculation)**

Bioburden validation test results(Sample Lot: First batch)					
Sample ID	Counted	PF	Recovered per sample(CFU)	Confirmed Inoculation level(CFU)	ERF
1	22	1.5	33.0	52/48	0.66
2	18		27.0		0.54
3	25		37.5		0.75
4	16		24.0		0.48
5	21		31.5		0.63
Average	20.4	NA	30.6	50	0.61
C.F (Correction Factor)		1.7			

✧ **Bioburden test**

Bioburden Test Result (Sample Lot: First batch)						
ID	CFU count		CFU Counted	P.F	C.F	CFU/ SIP sample
	Aerobes	Fungi				
1	1620	147	1767	3	1.7	9011.7
2	2240	259	2499			12744.9
3	2410	84	2494			12719.4
4	2520	138	2658			13555.8
5	1780	187	1967			10031.7
6	740	124	864			4406.4
7	960	67	1027			5237.7
8	1780	252	2032			10363.2
9	2520	51	2571			13112.1
10	1460	54	1514			7721.4
control	0	0	N/A	N/A	N/A	N/A
SIP Average	9890.4 CFU/SIP sample					
Batch 1 Average	**9890.4 CFU/Device**					

Bioburden Test Result (Sample Lot: Second batch)						
ID	CFU count		CFU Counted	P.F	C.F	CFU/ SIP sample
	Aerobes	Fungi				
1	1180	50	1230	3	1.7	6273
2	117	26	143			729.3
3	222	47	269			1371.9
4	680	32	712			3631.2
5	146	55	201			1025.1
6	210	51	261			1331.1
7	226	56	282			1438.2
8	123	85	208			1060.8

9	112	38	150			765
10	292	82	374			1907.4
control	0	0	N/A	N/A	N/A	N/A
SIP Average	1953.3 CFU/SIP sample					
Batch 2 Average	**1953.3 CFU/Device**					
Bioburden Test Result (Sample Lot: Third batch)						
ID	CFU count		CFU Counted	P.F	C.F	CFU/ SIP sample
	Aerobes	Fungi				
1	1460	152	1612	3	1.7	8221.2
2	2100	39	2139			10908.9
3	1760	56	1816			9261.6
4	980	56	1036			5283.6
5	1540	82	1622			8272.2
6	420	21	441			2249.1
7	680	95	775			3952.5
8	1440	65	1505			7675.5
9	1980	34	2014			10271.4
10	1460	127	1587			8093.7
control	0	0	N/A	N/A	N/A	N/A
SIP Average	7419.0 CFU/SIP sample					
Batch 3 Average	**7419.0 CFU/Device**					

✧ **Establishing sterilization dose**

Establishing sterilization dose			
Overall average bioburden(SIP)	Verification dose (SIP sample)	Overall average bioburden (Device)	Sterilization dose (10^{-6})
6420.9 CFU	13.6 Gy	6420.9 CFU	27.9 KGy

Note: Overall average bioburden= (batch1+batch2+batch3)/3= (9890.4+1953.3+7419.0)/3= 6420.9 CFU/device

✧ **Irradiation of verification dose**

Verification dose is irradiated on 100 samples (Lot: XN306301X) within the ±10% of target dose 13.6 kGy. Detail information refers to **Certificate of Irradiation for Test Sample** from **Sterigenics Shanghai E-Beam Co., Ltd (PO20130313128358)**.

✧ **Sterility test validation (Bacteriostasis & Fungistasis Test)**

Sterility Test Validation (B/F) Result			
Culture	*Bacillus subtilis* ATCC 6633	*Candida albicans* ATCC10231	*Aspergillus brasiliensis* ATCC16404
Test Sample	Positive	Positive	Positive
Inoculated Control	Positive	Positive	Positive
Inoculum Level(CFU)	31	39	30
Conclusion	The products of **Kimtech Pure A5 Sterile Sleeves** (Code: **36077**) do **not exist** bacteriostatic and fungistatic properties, or such properties have been **eliminated** through the test.		

✧ **Sterility test**

Sterility Test Result	
SIP	1.0
Sample number	100
Type of Media	TSB
Media Volume	400mL
Incubation Period	14 days
Incubation Temperature	28°C - 32°C
Results	2 Positive

- **Conclusion**

From validation results show, the product of **Kimtech Pure A5 Sterile Sleeves** (Code: **36077**) **PASS** the dose setting by using Method 1 according to ISO 11137-2. A sterility assurance level (SAL) of 10^{-6} is confirmed when irradiating the product by a sterilization dose of 27.9 kGy for routine production.

- **References**

✧ ISO 11737-1:2006 Sterilization of health care products - Microbiological methods - Part 1: Determination of the population of microorganisms on product

✧ ISO 11737-2:2009 Sterilization of medical devices---Microbiological methods---Part2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

- ISO 11137-2:2006 Sterilization of health care products---Radiation—Part 2: Establishing the sterilization dose
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==========End of report==========