

KIMTECH PURE* A5 Sterile Apparel



DATA PACK

Kimberly-Clark PROFESSIONAL*





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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:	DESIGN FEATURES:
Laboratory	 Suitable for EU GMP ISO 5 Grade A cleanrooms Gamma Irradiated, Sterility Assurance Level 10⁻⁶ Low Lint fabric, Helmke Drum test Category I 	 Unhooded coverall available in size S to 4XL Blue Indicator line to avoid touching outside Presented unzipped with inside-out fold
	 Bacterial Filtration Efficiency 96% Manufactured and Packed in ISO 5 cleanroom Vacuum packed for sterility assurance, saves space 	 Arms and legs telescope folded with snaps Waist and back panel elastics Elastic cuffs and thumb loops
The state case of the state state	 Certified PPE Cat III directive 89/686/EEC Type 6 limited chemical splash protection Type 5 particle protection Breathable barrier combines comfort and protection 	 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
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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.

and A



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.

THE OWNER OF THE OWNER OF	PERSONAL & PROCESS PROTECTION:	DESIGN FEATURES:
TERILE IR	 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 	 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.



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:	DESIGN FEATURES:
CE Sterileir	 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 	 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 Aseptic Parenteral Ophthalr ISO 5 Conde A Proceeding Orug Biotechnology Companyation produc	
ISO 5 Grade A Processing Manufacturing Compounding manufacture	Aseptic Hood





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		Re	esult
Particle shedding test (Helmke Drum)	IEST-RP-CC003.3 Catego			itegory l		
Bacterial Filtration Efficiency (3.0 µm	ASTM F2100 96			1%		
Bacterial Filtration Efficiency (3.0 µm	ASTM F2100		94	94%		
Particle filtration Efficiency (0.5 µm) -	ASTM F2299			94%		
Particle Filtration Efficiency (0.5 µm)	ASTM F2299		93	93%		
Abrasion resistance			EN 530 Metho	od 2	Cla	ass 3 of 3
Flex cracking resistance	ISO 7854 Method B		Cla	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		Cla	ass 1 of 3		
Resistance to ignition			EN 13274-4 Method 3		Pa	SS
Seam strength			EN ISO 13935-2		Cla	ass 3 of 3
EN ISO 6350:2005 – Resistance of penetration by liquids/chemicals.	CAS number	Penetration Class	Penetration %	Repellen Class	су	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.	Description	Code.
Coveralls, 25 per Case	88800 (S), 88801 (M), 88802 (L), 88803 (XL),	Integrated Hood & Mask, 75 per Case	36072
Dente View Fact we have	88804 (2XL), 88805 (3XL), 88806 (4XL)	Hood with Ties, 100 per Case	25797 / 88807
Boots Vinyl Foot, 100 pairs per Case	12922 (S), 88808 (Universal), 12920 (XL)	Sterile Sleeves, 100 pairs per Case	36077
Boots Vinyl Sole, 100 pairs per Case	31683 (S), 31696 (Universal), 31697 (XL)		

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isit www.sthttpching for more product information: includes data-packs, gowning posters and certificates of conformance & irradiation.



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



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

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

Step 9: Do the same with the other leg

Step 12: Slip thumbs through thumb loops

Final Step: Cross legs and zip up coverall

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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^{*} 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

(B) Kimberty-Clark

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KIMTECH PURE* A5 Sterile Cleanroom Apparel Label Design

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

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



<u>Please note:</u>

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.

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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)

REF 88808

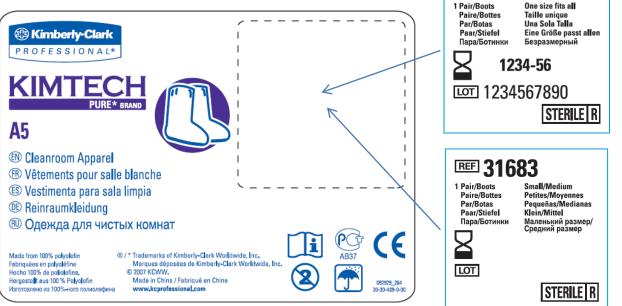
Case Label



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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	М	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:

Xiayh Wan

Date: May 29, 2012

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

Kimberly-Clark | 1400 Holcomb Bridge Rd., Roswell, GA 30076 USA,

Form# KP-FORM-00052/2

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你合同编号。 Sub-contract: GM12	070127			
客户名称	2002200	2.02 Sec.	RUSZJPY(B)-751	5 AC/01
Customer Kimb	erly-Clark Prof	essional	and the	Sec
产品名称 Article description	包装规格(厘米) Carton Size(cm)	产品 批号 Article Lot No.	教量(箱)	毛重(公斤)
Universal Boots:8880	50+30+37	XN218101X	Carton Qty(cs) #180#	G.W(kgs) 1620
8 Sleeve:36077 Coverall: 88802 Coverall: 88805 Universal Boats:8880 8 以下空白	50*30*37 50*30*37 50*30*42 50*30*37	XN2188011 XN213701X XN2137011 XN2138011	*62* *23* *76* *40*	334,8 158,4 045 360
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編照結束的日期 Irradiation lot finish da	te	2012-07-	15	ALC: Y
客户要求最低吸收剂量 Minimum specified dose:	32.5 kGy	最低刻量监测区级 Minimum inspection		4.0 kGy
客户要求最高吸收剂量: Maximum specified dose:	≌ 50 kGy	最高利量值测区级 Maximum inspection	收剂量: area dose; 4	4.6 kGy
松翰阳: Inspector: 13日1日 年秋:	2012.7.15	深圳市金鹏源		限公司
Approved: 7 10	1.15	SHENZHEN JPY	明分公司 'ION-TECH.C ING BRANCI	
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Statement internal lists

Protocol Number	Revee	Insue Oale	Boet Description of Revision
797100277-P	0	April 2, 2010	
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	2		

Protocol Ville

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

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

Prepared By	Zezcina Turnalis Consullani, Siar Pru Consuling	Oale
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Аррютей Ву	Niki Fidoviðslik Directori SteriPro Coueuring	Dale

Approved By

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<u>. 14</u>,2010

Spensor Contact:

Thereas McCoy

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Protocol Number	Revision	Issue Oate	Bret Description of Revision
797100277-P	0	April 12 2010	
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Protocol Title		
VD-Max	32.5 Radiation Validation for KI Cleanroom Sterile Appar	
SteriPro Consultar	ni. Zabrina Tumailis	· · · · · · · · · · · · · · · · · · ·
Sponsor Name an	nd Address	Sponsor Contact:
Kimberly-Clark 1400 Holcomb Bri Roswell, GA 3007		Theress McCoy
Prepared By.	Zahnna Tumaitis Consultanti SteriPio Consulling	
Roulawed By:		Date Date çitely signed by Niki Fidopiastis Nich-Niki Fidopiestis, to-Director of Consulting.
Approved Dy	Niki Fidopiastis 🔋	J-StenPur Amail-nfidoprastis@stergenics.com, 405 and.2010.04.14.07/34/02_97/00
Аррголед Ву	Пілески, StaliPra Consulling Direcku, StaliPra Consulling Плагеза М.Соу Кілођаљу-Clark	Date

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Protocol Number	Revision	Issue Date	Brief Doscoption of Revision
797100277-P	0	April 12, 2010	
	1		
	2		

Protocal Trille VD-Max32.5 Radiation Validation for KIMTECH PURE* A5 **Cleanroom Sterile Apparel** SteriPro Consultant, Zabrina Tumaitis, Sponsor Name and Address: Sponsor Contact Kimberly-Clark Theresa McCoy 1400 Holcomb Bridge Road Roswell, GA 30076 մնն Prepared By: Zebone Consultant, StenPro Consulting 0ate 4.1.3 7-3 Reviewed By Julie Arinaga Quality Assurance Manager, SteriPro Labs Approved By: Oste Nik: Fidopiastis Director, Ster Pro Consulting Approved By Oate Theresa Mr.Cry

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Terms and Conditions of Study

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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 Apparet. 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 Stenle Apparel - Coveralis - Size S
Kimlech Pure" AS Cleanroom Sterile Apparel - Coveral's - Size M.
Kimlech Pure" AS Cleanroom Sterile Apparel - Coveralis - Size L
Kimteon Pure" AS Cleanroom Sterile Apparel - Coveralls - Size XL
Kimtech Pure* A5 Cleanroom Storile Apparel - Coveralls - Size 2XL
Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralis - Size 3XL
Kimtech Pure* A5 Cleanroom Sterile Apparel - Coveralls - Size 4XL
Kimlech Pure* A5 Cleanroom Stenle Apparel - Coveralis - Size 5XL
Kimtech Pure* A5 Cleanroom Storile Apparel - Coveralls - Size 6XL
Kimtech Pure' A5 Cleanroom Stenle 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 Cloanroom Sterile Apparel - Bools - XL/2XL

2. Objectives

- 2.1. Preliminary bioburden data has determined the Kimtech Pure* A5 Cleantoom Starild Apparel -Coveralls - Size 6XL as the Dosd Setting Device for this starilization family
- 2.2 The Dose Setting Device for the product family will be the test sample for this validation. Prestonlization bioburden level will be determined to establish the appropriate verification dose.
- 2.3 Recommendation for a routing 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 10⁻⁸ 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.



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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 bioburdan for the overall average or a single for 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 pinnion (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 StenPro, 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 relain 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/AAMMISO 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. ONV 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.



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- 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 Melhod

- 7.1. Recovery Determination
 - 7.1.1.Efflorency 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 bipourden test results for each lot will be adjusted by applying the ERF, in order to obtain a theoretical bipburden estimate. This theoretical binburden 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 reputed 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. Ventication Dose Oetermination
 - 8.1.1.A venication dose will be determined using the tables specified in AAMI TIR 33. The verification duse 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 traduation 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.



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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 duse 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 tan 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 tenverification dose samples.

8 4, Test of Sterifily Melhod

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/jungistasis 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 steniity. 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.

- Verification is accepted if there are no more than one positive sterility test units out of the tentested.
- 9.2. If two positives accur, perform another sterility test on ten additional units that have been irradiated at the same verification dose determined above. Upon completion of the second stanlity 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, venification 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. Bactenostasis/Fungistasis test passes.



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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 balches 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 10⁴ 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 AN\$I/AAMI/ISO 11737-2:2009, Stentization of medical devices Microbiological methods Part 2: Tests of steniity 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, Ster/lization of health care products Radiation Part 2: Establishing the sterilization dose
- 11.5.AAM) TIR 33:2005, Sterifization of health care products Radiation Substantiation of a selected sterifization dose – Method VD-Max
- 11.6.USP/NF_U.S. Pharmacopoeia (current version).



BIOBURDEN TEST REPORT Procedure Reference: LB-MIC-004

					Date Receive	d:	03/29/10
	rdy-Clark	I	Product:		TECH PURE" A5	Cleans	om Sterile
	Holdemb Bridge Road ell, GA 30076		Call/ Part #:	129	arel- Bools 2XL 20		
			ot #:		07702X		
ustomer Specificat	ion Sheet# / Rev #:	1-004-411	Rev. 2	Efficiency	r Recovery Facto	or (ERF)): <u>N</u> (A
Test Me	<u>edia</u>	Manufactu		Lot			Date
Tryptic Soy Agar (TS		Biomere		ITME		-	4/10
Sabouraud Dextros		SteriPro		(T0170			7/11 3/11
Phosphate Buffered	Saline (P85):	SteriPri	3	170230	13143	0.94	arti
Sample Preparation:	: Each sample was in	nmersød.					
	Total Rinee Volum	в:200	mL ∵Volu		ad per Organis	-	
	Enumeration Meth		Pour Plate		Fillration		Surface
	TSA Incubation Te	mpératura:	30-35°C	SDA Inc	ubation Tempe	rature:	20-25°C
Date	t	Date TSA			Date SDA		
Extracted/Incubated	: <u>03/30/40 </u>	Enumerates); <u>(</u>	14/02/10	Enumerated	J;	04/05/10
Г	TEST RESULTS <u>(C</u>	olom Form	<u>ning Units (C</u> Aerobes		ungi-Yesst/Mold	1	
[Sample ID	olom Form	Aerobes (TSA)		ungi-Yessi/Mold (SDA)		
Ē	Sample ID		Aerobes (TSA) 12 <u>0</u>		ungi-Yesst/Mold		
Ē	Sample ID		Aerobes (TSA)		ungi-Yessi/Mold (SDA) <5		
	5ample ID 1 2		Aerobes (TSA) 120 120		ungi-Yessi/Mold (SDA) <5 <5		
	5ample ID 1 2 3 4 5		Aerobes (TSA) 120 120 130 115 135		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 <5 10		
	5ample ID 1 2 3 4 5 8		Aerobes (TSA) 120 120 130 135 135 235		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 10 5		
	5ample ID 1 2 3 4 5 8 7		Aerobes (TSA) 120 120 130 115 135 235 150		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 <5 10 5 10		
	Sample ID 1 2 3 4 5 8 7 8		Aerobes (TSA) 120 120 130 115 135 235 150 135		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 10 5 10 5		
	5ample ID 1 2 3 4 5 8 7		Aerobes (TSA) 120 120 130 115 135 235 150		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 <5 10 5 10		
	Sample ID 1 2 3 4 5 8 7 8 9 10 Total Average		Aerobes (TSA) 120 120 130 115 135 235 150 135 135 135		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 		
	Sample ID 1 2 3 4 5 8 7 8 9 10		Aerobes (TSA) 120 120 130 115 135 235 150 135 175 125		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 <5 10 5 10 5 5 <5 <5		
	Sample ID 1 2 3 4 5 6 7 6 7 8 9 10 Total Average Bloburden/David	C9 Spicablej	Aerobes (TSA) 120 120 130 115 135 235 150 135 150 135 125 144.0		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 10 5 10 5 5 5 5 5 5 5		0
Control Results:	Sample ID 1 2 3 4 5 8 7 8 9 10 Total Average Bioburden/Devi		Aerobes (TSA) 120 120 130 115 135 235 150 135 175 125		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 <5 10 5 10 5 5 <5 <5		0
Control Results: <u>Comments</u> :	Sample ID 1 2 3 4 5 6 7 6 7 8 9 10 Total Average Bloburden/David	C9 Spicablej	Aerobes (TSA) 120 120 130 115 135 235 150 135 150 135 125 144.0		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 10 5 5 5 5 5 5 5 0 9		0 -7 j
	Sample ID 1 2 3 4 5 6 7 6 7 8 9 10 Total Average Bloburden/David	C9 Spicablej	Aerobes (TSA) 120 120 130 115 135 235 150 135 150 135 125 144.0		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 10 5 10 5 5 5 5 5 5 5		0 -7 1 0
Comments:	Sample ID 1 2 3 4 5 6 7 6 7 8 9 10 Total Average Bloburden/David	C9 Spicablej	Aerobes (TSA) 120 120 130 115 135 235 150 135 150 135 125 144.0		ungi-Yessi/Mold (SDA) <5 <5 <5 <5 10 5 5 5 5 5 5 5 0 9		0 -7 1 0 -7/12

норысайол, StenPro Lack appressly states that it makes ou representation of example, regarding the adequary of the second or resting for any spectrum nor to recommend. The being me determined responsibility of the sponsioning clear. StanPro Laos' kabitly for any tes or determined for make electric or lattice to any encoded the cost of the testing performed, and BlenPro Laos' kabitly for any testion of while or consequential damages



BIOBURDEN TEST REPORT Procedure Reference: LB-MIC-004

SteriPro ^e Lai	bs ₩O#:	401710-MIC-004-	¥	Page	1	of	_ 1
				Date Receiv	ved"	03	/29/1D
Customer:		y-Clark Noomb Bridge Road , GA 30076	Product: Cat / Pert # Lot #:	RIMTECH PURE* / Apparel- Hood : 88807 AR007502X	A5 Clear	nronm	Sterile
Customer Sp	recificatio	n Sheet# / Rev #:	1-004-411/ Rev. 2	Efficiency Recovery Fa	ctor (EF	lF).	<u>N/A</u>
	Tesl Med	la -	Manufacturer	Lot No.	<u>Ex</u>	p. Dat	2
Tryplic Soy .	Agar (TSA	<u>b:</u>	Biomeneux	ITMER432	-	07/14/10 03/17/11	
Sabouraud (SteriPro	IT01703132	03		
		aline (PBS):	SteriPro	(T02303143	D	3/23/11	1
<u>Sample Prep</u>	paration:	Each sample was w	mmersed				
		Total Rinse Volum	e: 200mL Volu	ume Extracted per Organ	işm Ty) #:	40ml
		Enumeration Meth	ied: Pour Plat	ter X Fill⊮ation		Surf	ace
			—				20-25
		TSA Incubation Te					
Date			Date TSA	Date SDA			NE-40
Extracted/in	cubated:	03/30/10	Enumerated:	Q4/02/10 Enumerat	MANGI	1141	05/10

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

Sample ID	Aerobes (TSA)	Fungi-Y+349Mold (SDA)
1	175	<5
2	210	30
3	200	5
4	18Q	5
5	175	5
- e	200	<5
7	215	10
\$	190	5
9	270	15
10	125	10
Total Average Bloburden/Device (calculated with ERF II applicable)	194.0	9.5

Control Results:	ABT		SDA	0	P83 <u>0</u>	
<u>Comménis</u> :	. N	()	dr.			
Prepared By:		<u>K 4 ([</u> 4	/JUN	Date:	<u>_ 4[7]/0</u>	
Reviewed By:		<u> Antinez</u>		Date:	11/7/10	

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BIOBURDEN EXHAUSTIVE RECOVERY VALIDATION TEST REPORT

Procedure Reference: LB-MIC-004

SteriPro [®] Labs WO#	401712-MIC-004	4			Page .	1	of	2
					Date Receiv	ed:	03	(29/10
1400 H	ly-Clark Iolcomb Bridge Road II, GA 30076	C,	oduct: (L) Part # it #:	Арры 12914	ECH PURE1A rel-coveralis-6 4 7602A		nroom	Sterile
Customer Specificatio	on Shouf#/Rev #:	-004-411/	Rev 2	Efficiency	Recovery Fac	;lor (El	RF):	NØ
<u>Test Mar</u> Fryptic Soy Agar (TS) Sabouraud Dextroso Phosphate Buffered -	A); Agar (SDA):	<u>Manufactur</u> Biomerieu: SteriPro StenPro		Lot N ITMFR4 IT01703 IT02303	437 132	0	o <mark>rp. Da</mark> 17/29/1 13/17/1 13/23/1	0
Sam <u>ole Preparation</u> :	For each sample, a	an SIP of 10% :	was cul a	nd immersed	in PBS			
	Total Rinse Volun	ne. 200m	LVoi	uma Extract	ed per Organ	işm Ty	n pe :	40 m
	Enumeration Meth		Pour Pla		Filtration			1868
	TSA Incubation T	emperature:	30-35°(SDA Inci	ibation Temp	eratur	9 :	20-25
Data Extracted/incubated:	04/01/10	Date TSA Enumerated:	_	<u>04</u> /0 <u>5/10</u>	Date SDA Enumerat	ed: _	04	/06/10
See Following Pag	e(s) for Repetilive	Wash Resul	ts					
Calculated Efficiency	r Recovery Factor (E	ERF):	<u>0.2</u> 7					
<u>Çommenla</u> :								

Prepared By:	der and	Date:	<u>4/10/10</u>
Reviewed By:	<u>— Rogel Marsay</u>	Date:	

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Procedure Reference, LB-MIC-004



SteriPro[®] Labs WD#:

401712-MIC-004-0

Page 2 of 2

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

FIRST WASH

\$ample ID	Aerobea (TSA)	Fungi-Yesst/Mold (SDA)
1	1850	50
2	2200	150
3	1050	50
4	1850	<50
5	1200	50
Total Average Bioburden/Device	1630	70

SECOND WASH

Sample 1D	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

THIRO WASH

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

Control Results:	TSA	<u> </u>	SDA	n	PBS	0
------------------	-----	----------	-----	---	-----	---

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BIOBURDEN TEST REPORT Procedure Reference: LB-MIC-004

	401709-MIC-004-I				₽aãe 7	1	o -	
					Date Receiv	ed:	03/	28/10
	ly-Clark	Pro	duct:		ECH PURE" A		nroom S	Sterfe
	olcomb Bridge Ruad	_			rei- Coveralis-(SXL .		
Roswei	II, GA 30078		t / Part #:	1291/				
	_	Loi	t 4 ;	AROU	7602A	_		
ustomer Specificatio	on Sheet# / Rev #:	1-004-411/ R	ev. 2 i	Efficiency I	Recovery Fac	tor (EF	IF);	0 27
Tasi Me	dia	Manulaçture	r	Lot N	<u>o.</u>	Ex	o. Date	2
Tryptic Soy Agar (TS/		Biomeriaux		ITMER		0	7/14/10	
Sabouraud Dextrose		SjeaPro		LT01703	132		3/17/11	
hosphate Buffered	Saline (PBS):	\$ler.Pro		1102303	143	0:	3/23/11	
<u>Sample Proparation</u> :	An SIP of 10% of sar	mple was cut a	and immed	sed.				
	Total Rinse Volume	r:200 <u>m1</u>	Volun	ne Extract	ed per Organi			40mL
	Enumeration Melho				Filuation		Surf	
	TSA Incubation Ter	nperature:	30-35°C	ŞDA Incu	ibation Temp	eraturé	n: 2	0-25 ⁴ C
Date	D	ate TSA			Date SDA			
Extracted/incubated:	03/30/10 E	numerated:	0	4/02/10	_ Enumerate	id: _	04/0	<u>)5/10</u>
-	TEST RESULTS (Co	olony Formin				.		
Γ	TEST RESULTS (Co Sample ID	olony Formin	g Units (C Aerobes (TSA)		<u>evice):</u> Igi-Yeast/Mol (SD <u>A)</u>	ť		
F	Sample ID	Nony Formin	Aerobes (TSA) 1750		ngi-Yeast/Mol (SDA) <50	t -		
	Sample ID 1 2	Plany Formin	Aerobes (TSA) 1750 1800		191-Yeast/Mol (SDA) <50 200			
	Sample ID 1 2 3	olony Formin	Aerobes (T8A) 1750 1800 1850		191-Yeast/Mol (SDA) <50 200 50			
	Sample ID 1 2 3 4	Jony Formin	Aerobes (TSA) 1750 1800 1850 3050		191 Yeast/Mol (SDA) <50 200 50 50			
	Sample ID 1 2 3 4 5	Plany Formin	Aerobes (T8A) 1750 1800 1850 3050 2250		191 Yeast/Mol (SDA) <50 200 50 50 150			
	Sample ID 1 2 3 4 5 6	Plany Formin	Aerobes (TSA) 1750 1850 1850 3050 2250 1700		191 Yeast/Mol (SDA) <50 200 50 50 150 200			
	Sample ID 1 2 3 4 5 6 7	Plany Formin	Aerobes (TSA) 1750 1850 1850 3050 2250 1700 2950		191 Yeast/Mol (SDA) <50 200 50 50 150 200 100			
	Sample ID 1 2 3 4 5 6 7 8	Plony Formin	Aerobes (TSA) 1750 1850 1850 2250 1700 2950 2000		reast/Mol (SDA) <50 200 50 50 150 200 100 100 150			
	Sample ID 1 2 3 4 5 6 7 6 9	Plony Formin	Aerobes (TSA) 1750 1850 1850 3050 2250 1700 2950		191 Yeast/Mol (SDA) <50 200 50 50 150 200 100			
	Sample ID 1 2 3 4 5 6 7 8		Aerobes (TSA) 1750 1800 1850 3050 2250 1700 2950 2950 2000 2750		reast/Mol (SDA) <50 200 50 50 150 200 100 150 200			
	Sample ID 1 2 3 4 5 6 7 6 7 6 9 10 Total Average Bioburden/Devic (calculated with ERF, it app		Aerobes (TSA) 1750 1800 1850 3050 2250 1700 2950 2950 2950 2950 2750 1950 8166.7		reast/Mol (SDA) <50 200 50 50 150 200 100 100 150 200 200 500-0			¢
Control Results:	Sample ID 1 2 3 4 5 6 7 6 9 10 Total Average Bioburden/Dev/c		Aerobes (T8A) 1750 1850 3050 2250 2750 2950 2950 2750 1950		reast/Mol (SDA) <50 200 50 50 150 200 100 100 150 200 200 500-0		_	¢
Control Results: <u>Comments</u> :	Sample ID 1 2 3 4 5 6 7 6 7 6 9 10 Total Average Bioburden/Devic (calculated with ERF, it app		Aerobes (TSA) 1750 1800 1850 3050 2250 1700 2950 2950 2950 2950 2750 1950 8166.7		reast/Mol (SDA) <50 200 50 50 150 200 100 100 150 200 200 500-0		-	<u>c</u> /
<u>Comments</u> :	Sample ID 1 2 3 4 5 6 7 6 7 6 9 10 Total Average Bioburden/Devic (calculated with ERF, it app		Aerobes (TSA) 1750 1800 1850 3050 2250 1700 2950 2950 2950 2950 2750 1950 8166.7		(SDA) <50 200 50 50 150 200 100 150 200 200 500.0 500.0		-	<u>•</u>
	Sample ID 1 2 3 4 5 6 7 6 7 6 9 10 Total Average Bioburden/Devic (calculated with ERF, it app		Aerobes (TSA) 1750 1800 1850 3050 2250 1700 2950 2950 2950 2950 2750 1950 8166.7		reast/Mol (SDA) <50 200 50 50 150 200 100 100 150 200 200 500-0		-	<u>ہ</u>
<u>Comments</u> :	Sample ID 1 2 3 4 5 6 7 6 7 6 9 10 Total Average Bioburden/Devic (calculated with ERF, it app		Aerobes (TSA) 1750 1800 1850 3050 2250 1700 2950 2950 2950 2950 2750 1950 8166.7		(SDA) <50 200 50 50 150 200 100 150 200 200 500.0 500.0		-	<u>ہ</u>

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BIOBURDEN TEST REPORT

Procedure Reference: LB-MIC-004

SteriPro [®] La	bs WO#.	407027-MIC-004-	I			Page	<u> </u>	ં	1
						Date Recei	ived:	04	u07/10
Customer:		y-Clavk bloomb Bridge Road I, GA 30076	Cat / P Lot #:		Appar 12914	ECH PURE el-Coverañs H 0402B		inródň)	Sterile
Customer Sj	pecificatio	n Sheet# / Rev #:	1-004-411/ Rev.	3 <u></u> E	fficiency l	Recovery Fi	actor (E	RF]:	0.27
<u>Test Media</u> Tryptic Soy Agar (TSA): Sabouraud Destrose Agar (SOA): Phosphate Buffered Saline (PBS):		<u>Manufacturer</u> Biomerieux SteriPro SteriPro		Lot No. (TMFR437 (T01703132 (T00104165		(<u>Exp. Data</u> 07/29/10 03/17/11 04/01/11		
<u>Sample Prej</u>	paration:	Each SIP of 10% w					7		40mL
Date Extracted/In	ncubated:		nod: Pour emperature: 30 Date TSA Enumeratod:	r Plate 35°C 04	X _ SOA Inc. 12/10	ad per Drga Filtration Ibation Tem Date SDA Enumera evice):	iperatur L	Şur Te:	face 20-25 ⁰ C
	Γ	Sample ID		robes TSA)	Fur	igi-Yeast M (SDA)	þið		
		1		2300		150			
		2		3200		200			
		3		2350		100			
		4		285 <u>0</u>		<50			
		5		5250		<50			
		6		4500		100			
		7		3400		50			

Control Results:	TŜA .	U	SDA	<u>0</u>	PBS	_ •
<u>Comments</u> :	10	0	۱			. d
Prepared By:	<u>_All</u>	K La	AD.	Dətə:	<u> </u>	14(10_
Reviewed By:	Bugh	<u>Africasa</u>		Date:		<u>19[©</u>

2000

3250

1850

11463.0

9

9

10_____ Total Average

Bioburden/Device [calculated with ERF IV applicable] <50

50

50

314.8

The lest results revele only in the samples as provided and resided. This report may not be reproduced, except which without under approval from RenPro Labs

Simulho Laos angressiy staine that it makes no representation or martanly regarding the solid quacy of the samples automized for lesting for any specify use or application. That davig me determinant industriability of the sponeousy cherr. Stonflip Labs thereby his any lass or parage resulting from its actions or failure () act shall not exceed makessi of me testing performed, and Stenflip Labs shall not be laber for any incidental or consequential damagea



BIOBURDEN TEST REPORT Procedure Reference: LB-MIC-004

SteriPro [©] Labs WO#	407026-MIC-004-I	I	Page	• <u>1</u>	of <u>1</u>
			Date Rec	ceived:	04/07/ <u>10</u>
1400	erly-Clark Holcomb Bridgo Road ell, GA 30076	Product: Cat∫ Part Lot ≉:	KIMTECH PUR Apparel-Covera #- 12914 AR010402C		nom Sterke
Customer Specificat	tion Sheet# / Rev #: _	1-004-411/ Rev. 3	Efficiency Recovery	Factor (ER	=): <u>0.27</u>
<u>Test Mi</u> Tryplic Soy Agar (13 Sabouraud Destross Phosphate Buffared Sample Preparation	SA): e Agar (SDA): i Saline (PBS):	<u>Manufacturer</u> Biomerieux SteriPro SteriPro as cut and immersed i	Lot No. (TMFR437 (TC1703132 (TC0104165 in PBS.	07) 03(). <u>Date</u> /25/10 /17/11 /01/11
	Total Rinae Volum	e: 200mL Vo	Sume Extracted per Or	<u>ganism</u> Тур	9: 40mL
	Enumeration Meth				Surface
	TSA incubation Te	mperature: 30-35	C SDA Incubation Te	emperature:	20-25°C
Date Extracted/incubated	a: 04 <u>/08/10</u>	Dala TSA Enumeratod:	Date S 04/12/10 Enume s (CFU) per Device):	iDA erated:	04/13/10
Г		Aero		Mold	
	Sample ID	(TS			
-	<u>1</u>	428		— i	
ł		209			
ł	- 4	21			
	5	394			
	6	310			
	7	184			
	8	22			
	9	27			
	10 Total Average Bioburden/Dev Jeakulated with CRF, If ap	ice 110'			
Control Results:	TSA	ść)A	P85	0
Comments:	L			ſ	
Prepared By:	<u>dl</u>	<u>uk Cast</u>	Date:	્ય	1440
Reviewed By:	<u>لمور شریع</u>	<u> 111: 142 -</u>	Oate:		<u>/14/60</u>

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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 Apparal, 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: Mothod VD-Max30 guidelines, the Sub-process Venification 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) <u>As colony forming units (cfu) per device</u>
AR007602A	8565 7 cfu/device
AR010402B	11777 8 clu/device
AR0104020	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 SLP verification dose calculation, the verification dose was determined threatly 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, tan units 0! product should be sampled from a single production lot and irradiated at the vertication dose of 9.9 kGy \pm 10% After irradiation the samples will be sent to Ster/Pro Labs to be placed on test of sterility

It 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 Tegards.

Zabrina Tumaitis Crosultant, SteriPro Consulting

Certificate of Processing

STERNGENICS 344 Bonnis Circle Corone CA 92880 TEL 951 340-0700 FAX www.sterigenice.com

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45	iD CO	More	m Cross		9.4 kGy Ideasta		JGANGIA Joge ()audia Tost	Q4/19-1	A.28GMT (נ
45	ia no	Манля	um Oose		10.2 ×Gy Hoaso		JGARCIA Jose Garcia Tesi	04/19/1	0.0139-04.6331

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ine dosimelry system employed.

Electronically Signed By

Annete Posete Werk Older Compioxons Date 04/19/10 16:00/47 GVT



STERILITY VALIDATION (B&F) TEST REPORT

Procedure Reference: LB-MIC-027

SteriPro [®] La	bs WO#: 415045-MIC	-027-1			Pa	90 <u>1</u>	of	_1
Date Receiv	ed: 04/20/10	Date On-Te	st: <u>04/</u> 2	1/10	Date Off	l-Test: <u>(</u>	14/26/11)
Customer:	Kimberly Clark 1400 Holcomb Bridge I Roswell, GA 30076	Road		rt#:	KIMTECH Sterile Ap 12914 AR00760 N/A 412952 04/19/10	opare⊢ Co 28		
Ţ	est Media	<u>Manufacti</u>	JIBI	<u>Volume</u>		<u>t No.</u>		Date
	TSB	StenPro	5	3000mL		204185 904195		12/11 19/11
Product Ster	rility Customer Specific	cation Sheet	# / Revis	ion: <u> - </u>	036-797/R	ev. 0		
<u>Test Method</u> Immersion of <u>Test Results</u>	SIP	4\$5		FAIL		·B		1
	ORGANISM			Contro			Sample	
Bacillus subt	ilis (ATCC #8633)			+			+	i
Candida albicans (ATCC #10231)				+	+		+	
Aspergillus nigar (ATCC #18404)				+	I		+	
<u>Comments</u> : Prepared By Reviewed B		1027		124-	Date: Date:	_ <u>4/2</u>	<u>7/17</u>	<u>)</u>

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SteriPro Labs expression liver in the moment of personnal for or nerrority regarding the sciency of the samples submitted for any specific day specific day specific day specific day specific day in a second in a second line for any list of days and strange resulting for any specific day of the specific day of the second second line for any list of the testing performed, and SteriPro Labs shall not be table for any venderial or consequential dampets.



PRODUCT STERILITY TEST REPORT

Procedure Reference: LB-MIC-036

SterlPro ⁵ Labs WC	0#: <u>415039-M</u>	IC-036-I		Page <u>t</u>	_ of1
Date Received:	04/20/10	Dat o On-Test:	04/21/10	Date Off-Test: _	05/05/10
1400	perty –Clark) Holcomb Bridg well, GA 30076	e Road Cat. Lot: Loa Ster		KIMTECH PURE*/ Sterile Appareal-Co 12914 AR0075028 AR0075028 412952 04/19/10	
T <u>est M</u>	ledia	Manufacturer	Volume	<u>Lat No.</u>	<u>Exp. Date</u>
⊤ryptic Soy B	iroth (TSB)	StenPro Labs	3000m L	IT01204185	04/12/11
Number of Sampl	es: <u>10</u>	_			
Customer Specifi	cation Sheet# J	Revision #:	6-79 <u>7/ Rev. 0</u>		
<u>Test Melhod:</u> Immersion of SIP.					
<u>Test Results</u> : TSB: Open Control: Results Meet Crit	<u>x</u>	No Growth No Growth X YES	NO	_ Growth _ Growth	
Atlachments Incl	luded: N/A				
<u>Comments</u> :	N/A				
Prepared By:	_dfi	<u>x (tast</u> nem Be		Date:	50

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No.: DS004-13r

Rev 0

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

They she sold-of-of

Reviewed by Date

Seagle Xu Approved by

Date Chingen Mc Cony 293-04-01 Kimberly-Clock Philosinal

Revision

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

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No.: DS004-13r

Rev 0

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)

Sample ID	- Counted	PF	Recovered per sample(CFU)	Confirmed Inoculation level(CFU)	ERF	
1	14		28		0.56	
2	13		26		0.52	
3	14	2.0	28	52/48	0.56	
4	13				26	
5	10		20		0.40	
Average	12.8	NA	25.6	50	0.51	
C.F (Corre	ection Factor)			2.0		



Rev 0

Bioburden test

	CFU	truce					
ID	Aerobes	Fungi	CFU Counted	P.F	C.F	CFU/ SIP sample	
1	164	87	251				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	4	2,0	3424	
7	98	45	143			1144	
8	125	8	133			1064	
9	147	48	195				
10	127	64	191			1528	
control	0	0	N/A	N/A	N/A	N/A.	
SIP Average			1810.4 C	FU/SIP samp	ole		
Batch 1 Average			1810.4	CFU/Device	0		
	Biobu	urden Test R	esult (Sample	Lot: Second	d batch)	And Managers	
144	CFU	count 🖂	CFU		C.F	OFLUCID	
ID	Aerobes	Fungi	Counted	P,F	Q.F	CFU/ SIP sample	
1	259	67	326			2608	
2	91	40	131			1048	
з	301	68	369			2952	
4	424	42	466		2.0	3728	
5	147	52	199	4	2.0	1592	
6	324	124	448			3584	
7	235	68	303			2424	
8	184	10	194			1552	

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9	242	62	304			2432	
10	187	74	261			2088	
control	0	0	N/A	N/A	N/A	N/A	
SIP Average		1211	2400.8 C	FU/SIP samp	ple		
Batch 2 Average			2400.8	CFU/Device			
	Biob	urden Test	Result (Sample	Lot: Third	batch)		
ID	CFU o	count	CFU	P.F			
IU.	Aerobes	Fungi	Counted	P.F	C.F	CFU/ SIP sample	
1	145	56	201			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	4	2.0	2464	
7	88	79	167				1336
8	98	25	123			in the task	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 C	FU/SIP samp	ole		
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 Vali	dation (B/F) Result	and the state of the
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	그 옷에 있는 것 같아요? 아무 것 같아요? 같아요? 같아요?	Pure A5 Sterile Integrated riostatic and fungistatic pro ough the test.	server and the server and the server of the

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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- 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

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No.: DS005-13r

Rev 0

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 Sleaves

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

Signature

2013-04-01 76 Edited by Date

2012-04-0 Reviewed by Date

2013-04-0 Seagle VA Approved by Date

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Revision

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

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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)

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 (Corre	ction Factor)			1.7		

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Bioburden test

De Traks in	Biol	ourden Test	Result (Sampl	le Lot: First	batch)	
ID	CFU count		CFU	DE	C.F	OF WORD
	Aerobes	Fungi	Counted	P.F	G.F	CFU/ SIP sample
1	1620	147	1767	3		9011.7
2	2240	259	2499		1.7	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 C	FU/SIP sam	ple	
Batch 1 Average	9890.4 CFU/Device					
	Biobu	ırden Test R	esult (Sample	Lot: Second	d batch)	
15	CFU count		CFU	P.F	C.F.	CFU/ SIP sampl
ID	Aerobes	Fungi	Counted	P.F	C.F	Crorse sample
1	1180	50	1230		1.7	6273
2	117	26	143	3		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



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9	112	38	150			765
10	292	82	374		12	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					
	Biob	urden Test	Result (Sample	Lot: Third	batch)	
ID	CFU count		CFU		-	
IU.	Aerobes	Fungi	Counted	P.F	C.F	CFU/ SIP sample
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

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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 Vali	dation (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	FR 541 51 51		

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

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

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