



KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves

Engineered for Protection. Designed for Comfort.



DATA PACK

Engineered for Protection, Designed for Comfort

KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves

KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves offer Improved Performance and Comfort and are Better for the Environment.

- Recommended for ISO Class 3 or higher cleanroom environments
- Contain no natural rubber latex reducing the potential for TYPE I glove-associated reactions
- Static dissipative in use
- Safe handling of objects due to improved and consistent grip
- Hand specific
- Walled & pouched in polyethylene for cleanroom use
- Packaged for aseptic donning
- Certificate of Analysis (by Lot) and Certificate of Irradiation available online
- Trend Data available online to demonstrate product quality over time

Improved Performance

Our innovative STERLING* manufacturing technology enables us to deliver a comfortable nitrile glove with all the protection and cleanliness our customers have come to expect. The result is a sterile nitrile glove combining the sensitivity of latex with the protection of nitrile.

Improved Comfort

When double-donned, the KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves deliver the equivalent thickness of a single latex glove without the risk of Type I latex allergic reactions. This improves feel & dexterity without any loss in barrier protection or performance.

Better For The Environment

The KIMTECH PURE* G3 Sterile STERLING* Nitrile Glove is also an environmentally responsible glove that requires fewer raw materials to produce. We have improved packaging to deliver 50% more gloves per case than traditional gloves. Average use of 25 cases per month results in a reduction of 1,000 kg of waste per year vs. traditional latex gloves.



CE 0123





KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves

Product Specifications

- Synthetic nitrile polymer (Acrylonitrile Butadiene)
- Contains no natural rubber latex.

Quality Standards

- This is a PPE Category III product classified by EC Council Directive 89/686/EEC. It is tested in accordance with the EN Norms EN420:2003
- Cleanroom packaged to meet the standard of ISO Class 3 Cleanroom
- Meets or exceeds AQL level of 1.5 for pinholes
- Manufactured in accordance with Quality System ISO 9001
- Dexterity Classification (EN 420:2003) = 5

PACKAGED FOR
ASEPTIC DONNING

EXCELLENT DEXTERITY
& TACTILE SENSITIVITY

POWDER-FREE

LOW ENDOTOXIN

LATEX-FREE

BEADED CUFF

30cm LENGTH

FULLY
TEXTURED

PHYSICAL PROPERTIES (Target values)

Characteristics	Value	Test Method
Freedom from holes	1.5AQL ¹	EN374-1 and ASTM D 5151
¹ AQL as defined per ISO 2859-1 for sampling by attributes		
Tensile Properties	Tensile Strength	Ultimate Elongation
- Before Aging	42 MPa	650%
- After Accelerated Aging	38 MPa	550%
ASTM D 412 and ASTM D 573		
Dimensional	Measured Point	mm
- Thickness	Middle Finger	0.10
	Palm	0.08
	Cuff	0.07
ASTM D 3767 and D 6319		
Palm Widths		
- Width (mm)	6 6.5 7 7.5 8 8.5 9 10	
	80 87 94 98 109 114 120 128	ASTM D 3767 / D 6319 and EN420
Particles (maximum)		
- Per cm ² > 0.5 micron	1500	TEST-RP-CC005
Endotoxin (maximum)		
- Endotoxin Units/pair	20	LAL Kinetic Turbidimetric Method

KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves

Size and Code	30cm
	10x
6	11821
6.5	11822
7	11823
7.5	11824
8	11825
8.5	11826
9	11827
10	11828



Reduce Today, Respect Tomorrow is the KIMBERLY-CLARK PROFESSIONAL* approach to sustainability. It begins with the understanding that the way we use resources today shapes the world of tomorrow. And it has led us to focus on reducing consumption at every stage of the product lifecycle – from design and manufacture to distribution and disposal. Reduction is the key to lowering the environmental impact of our activities as well as those of customers. It has also been crucial in achieving our number one position five years in a row on the Dow Jones Sustainability Index. To learn more about Reduce Today, Respect Tomorrow and how we can reduce consumption in your business, visit www.kcpreducetoday.com



INFORMATION SERVICE

For technical enquiries please email infofax@kcc.com
For sales enquiries please email kimtech.support@kcc.com

www.contaminomics.com

Contaminomics

KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves Donning Procedure

The Science of Protection.

Before starting the donning procedure, wash hands thoroughly and dry.

Step 1

Peel open sterile pouch and unfold glove wallet
(DO NOT touch the exterior surface of gloves).
Pinch the sides of wallet to open.



Step 2

Apply first glove to hand by sliding palm up into glove (thumb facing outward). Bend thumb toward center of palm and slide into glove while pulling up on the cuff. Leave the cuff rolled up.



Step 3

Apply second glove to hand by sliding the four gloved fingers into cuff of the second glove. Slide ungloved palm (thumb facing outward) into glove. Bend thumb toward center of palm and slide into glove while pulling up with fingers of gloved hand.



Step 4

Complete donning the gloves by pulling up the cuff of the first glove with the fingers of the second hand†.



Step 5

If double donning is desired, repeat steps 1-4 with a second set of gloves - this time using a half inch size larger glove if necessary.



www.contaminomics.com

KIMTECH
PURE* BRAND

† Isopropyl Alcohol (IPA) may be used to clean the surface of the gloved hands if required by standard operating procedure (SOP)

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CERTIFICATE OF ANALYSIS

Product Description : KIMTECH PURE*G3 Sterile Nitrile Gloves, 12" Hand-Specific Pair
(Formerly SAFESKIN* Sterile Critical Nitrile Gloves)

Catalog Numbers : 11821, 11822, 11823, 11824, 11825, 11826, 11827, 11828

Lot # : 971190 Total Cases per Lot : 573
Batches : SM93052VX to SM93342VX Date of Manufacture : Nov-09

Physical Test Data						
	Watertight	Dimensions	Visual Defects		Elongation (%)	Tensile (MPa)
			Minor	Major	Pre Aging	Pre Aging
Sample Size :	1410	672	1410	1410	384	384
AQL Level :	1.5	2.5	4.0	2.5	2.5	2.5
Failures Allowed per AQL :	35	21	88	53	12	12
Failures :	3	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept
Averages :					589	35.7

Test Methods : Watertight ASTM D 5151, Elongation and Tensile ASTM D 412

Particle Test Data				
Particle Size (µm)	Min	Max	Standard Deviation	Average Particles/cm ²
0.5 - 1.0	396	1067	142	597
1.0 - 2.0	35	119	23	70
2.0 - 5.0	11	47	10	26
5.0 - 10.0	1	8	2	3
10.0 - 20.0	0	2	1	1
>20	0	0	0	0
Total per Sample	466	1194	156	697

Test Method : IEST-RP-CC005

Extractable Ion Test Data							
	Anions Results						
	Fluoride F ⁻	Chloride Cl ⁻	Nitrite NO ₂ ⁻	Bromide Br ⁻	Nitrate NO ₃ ⁻	Phosphate PO ₄ ⁻³	Sulfate SO ₄ ⁻²
µg/g glove	<0.5	16.2	<2.5	<2.5	11.4	<5	2.1
µg/cm ²	<0.003	0.074	<0.016	<0.016	0.052	<0.031	0.013
	Cations Results					Trace Element Results	
	Sodium Na ⁺	Ammonium NH ₄ ⁺	Potassium K ⁺	Magnesium Mg ⁺²	Calcium Ca ⁺²	Zinc	
µg/g glove	1.1	0.9	1.6	<0.25	9.9	4.1	
µg/cm ²	0.005	0.004	0.007	<0.002	0.045	0.019	

Test Method : IEST-RP-CC005

Endotoxin Data		
Test Result:	0.429	Endotoxin Units/device (pair)
Specification:	< 20	Endotoxin Units/device (pair)

Test Method: Limulus Amebocyte Lysate (LAL) Test: Kinetic Turbidimetric Technique

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Review By : *Penn B.*
(QA Executive - SSMT)

CERTIFICATE OF IRRADIATION

Number: **MA**

0025517

SAF005

SAFESKIN MEDICAL & SCIENTIFIC (THAILAND) LTD
200 Moo 8, KANJANAVANICH ROAD
TAMBOL PRIK
AMPHUR SADA0, SONGKHLA
THAILAND
90120



ISOTRON MALAYSIA Sdn Bhd
Company No 512058-V
Kuala Ketil Industrial Estate
09300 Kuala Ketil, Kedah

Tel: 60 (0) 4 415 1111
Fax: 60 (0) 4 415 1110
<http://www.isotron.com>

Cust. Ref: 4027001171
Date Rec'd: 02/12/09
Date: 04/12/09

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS																																																																																																
M1SAF0050021 M209120023	KIMTECH Pure* G3, Sterile Sterling * Nitrile Gloves, 12" Hand Specific Pairs	546	<table><tr><th>CAT NO</th><th>MFG LOT/BATCH NO</th><th>QTY</th></tr><tr><td>11821-07</td><td>971190/SM93312VX</td><td>25</td></tr><tr><td>11821-07</td><td>971190/SM93332VX</td><td>11</td></tr><tr><td>11822-07</td><td>971190/SM93282VX</td><td>16</td></tr><tr><td>11822-07</td><td>971190/SM93322VX</td><td>20</td></tr><tr><td>11822-07</td><td>971190/SM93322VX</td><td>15</td></tr><tr><td>11822-07</td><td>971190/SM93322VX</td><td>19</td></tr><tr><td>11823-07</td><td>971190/SM93282VX</td><td>1</td></tr><tr><td>11823-07</td><td>971190/SM93282VX</td><td>33</td></tr><tr><td>11823-07</td><td>971190/SM93282VX</td><td>24</td></tr><tr><td>11823-07</td><td>971190/SM93292VX</td><td>12</td></tr><tr><td>11823-07</td><td>971190/SM93292VX</td><td>11</td></tr><tr><td>11823-07</td><td>971190/SM93322VX</td><td>21</td></tr><tr><td>11824-07</td><td>971190/SM93272VX</td><td>26</td></tr><tr><td>11824-07</td><td>971190/SM93302VX</td><td>10</td></tr><tr><td>11824-07</td><td>971190/SM93302VX</td><td>21</td></tr><tr><td>11824-07</td><td>971190/SM93312VX</td><td>15</td></tr><tr><td>11824-07</td><td>971190/SM93312VX</td><td>29</td></tr><tr><td>11825-07</td><td>971190/SM93272VX</td><td>27</td></tr><tr><td>11825-07</td><td>971190/SM93292VX</td><td>3</td></tr><tr><td>11825-07</td><td>971190/SM93292VX</td><td>29</td></tr><tr><td>11825-07</td><td>971190/SM93302VX</td><td>6</td></tr><tr><td>11825-07</td><td>971190/SM93302VX</td><td>25</td></tr><tr><td>11825-07</td><td>971190/SM93322VX</td><td>11</td></tr><tr><td>11826-07</td><td>971190/SM93292VX</td><td>4</td></tr><tr><td>11826-07</td><td>971190/SM93292VX</td><td>24</td></tr><tr><td>11826-07</td><td>971190/SM93292VX</td><td>14</td></tr><tr><td>11826-07</td><td>971190/SM93322VX</td><td>22</td></tr><tr><td>11827-07</td><td>971190/SM93292VX</td><td>18</td></tr><tr><td>11827-07</td><td>971190/SM93322VX</td><td>18</td></tr><tr><td>11828-07</td><td>971190/SM93292VX</td><td>17</td></tr><tr><td>11828-07</td><td>971190/SM93332VX</td><td>19</td></tr></table> IRRADIATION DATE: 03/12/2009 DOSE REQUIRED: 25.0-50.0 kGy ACTUAL DOSE RECEIVED: MIN:26.3 kGy MAX:36.1 kGy	CAT NO	MFG LOT/BATCH NO	QTY	11821-07	971190/SM93312VX	25	11821-07	971190/SM93332VX	11	11822-07	971190/SM93282VX	16	11822-07	971190/SM93322VX	20	11822-07	971190/SM93322VX	15	11822-07	971190/SM93322VX	19	11823-07	971190/SM93282VX	1	11823-07	971190/SM93282VX	33	11823-07	971190/SM93282VX	24	11823-07	971190/SM93292VX	12	11823-07	971190/SM93292VX	11	11823-07	971190/SM93322VX	21	11824-07	971190/SM93272VX	26	11824-07	971190/SM93302VX	10	11824-07	971190/SM93302VX	21	11824-07	971190/SM93312VX	15	11824-07	971190/SM93312VX	29	11825-07	971190/SM93272VX	27	11825-07	971190/SM93292VX	3	11825-07	971190/SM93292VX	29	11825-07	971190/SM93302VX	6	11825-07	971190/SM93302VX	25	11825-07	971190/SM93322VX	11	11826-07	971190/SM93292VX	4	11826-07	971190/SM93292VX	24	11826-07	971190/SM93292VX	14	11826-07	971190/SM93322VX	22	11827-07	971190/SM93292VX	18	11827-07	971190/SM93322VX	18	11828-07	971190/SM93292VX	17	11828-07	971190/SM93332VX	19
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	Total	546	Last page 1 of 1																																																																																																

This is to certify that the above items have been irradiated as specified above

JAYANTHIMALA . A

Authorised Signature: QA Manager
Isotron (Malaysia) Sdn. Bhd.
For and on behalf of **ISOTRON MALAYSIA Sdn Bhd**



Declaration of Conformity

Product: KIMTECH PURE* G3 Sterile STERLING* Nitrile gloves

Product codes:	KC Code	Size
	1182107	6.0
	1182207	6.5
	1182307	7.0
	1182407	7.5
	1182507	8.0
	1182607	8.5
	1182707	9.0
	1182807	10.0

Classification: PPE Category III

EEC Representative: Kimberly-Clark Professional Europe, Protective Clothing Business Group, 40 London Road, Reigate, Surrey, United Kingdom, RH2 9QP

Applicable Norms: Protective gloves against chemicals and micro-organisms (EN 374-1)
Protective gloves against mechanical risks (EN 388)
General requirements for gloves (EN420)

Kimberly-Clark Professional Europe, Reigate, Surrey, United Kingdom, RH2 9QP declares that Personal Protective Equipment: Protective gloves against chemicals and micro-organisms, model KIMTECH PURE* G3 Sterile STERLING* Nitrile gloves (product codes aforementioned) is in conformity with the provisions of EC Council Directive 89/686/EEC and with the harmonised standard EN 420, EN 388 and EN 374-1/3. The device is identical to the Personal Protective Equipment, which is the subject of EC certificate of conformity Number GB09/78686 issued by SGS United Kingdom (Notified Body 0120). This device is subject to the procedure set out in Article 11 point B of Directive 89/686/EEC under the supervision of the Notified Body TUV Product Service, Munich (Notified Body 0123).

Kimberly-Clark Corporation

A handwritten signature in black ink, appearing to read 'Larry Kludt'.

Larry Kludt
Global Regulatory Affairs Manager
Kimberly-Clark Europe



Kimberly-Clark

PROFESSIONAL*

KIMTECH

PURE* BRAND

G3 STERILE STERLING* NITRILE GANTS EN NITRILE STERLING

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 distributed in Australia by Kimberly-Clark Australia Pty. Limited, 52 Al
 Kimberly-Clark Europe Limited / Professional Sector, Reggate, Surrey
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 Господина Гельмана Невверенная, 52/1, Тел.: 007-495-725-4383
 www.kcorporational.com/ru

2020/04/2020

(EP) Tested for Watertightness and Low Chemical Protection
 Testés pour étanchéité à l'eau et faible protection chimique
 (DE) Geprüft auf Wasserdichtigkeit und geringen Schutz gegen
 Chemikalien
 (ES) Someridos a pruebas de impermeabilidad y protección
 contra sustancias químicas leves
 (PT) Comprovadas contra a estanqueidade à água e protecção
 contra produtos químicos fracos
 (JN) 水密性および軽度化学薬品性を検査済

(EN) Tested for Microorganism Hazards
 Testés pour les risques causés par les microorganismes
 (DE) Geprüft für Gefahren durch Mikroorganismen
 (ES) Someridos a pruebas contra riesgos presentados por
 microorganismos
 (PT) Comprovadas contra perigos apresentados por microorganismos
 (JN) 微生物危険性のテスト済み

[illegible]

NOTE: Must comply with Kimberly-Clark Master Manufacturing Specification

V1 07/21 SY

FOR ALL ART REQUESTS PLEASE E-MAIL -
kcpnateam@mathewbrandsolutions.co.uk
FOR ALL PLATE REQUESTS PLEASE E-MAIL -
pittsburghart@matw.com

August 26, 2009 • 096880MBS MG

SUBSTRATE :PET/PE Film

COLORS: PMS 267

Overall Lacquer Coverage



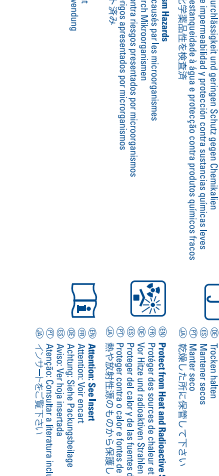
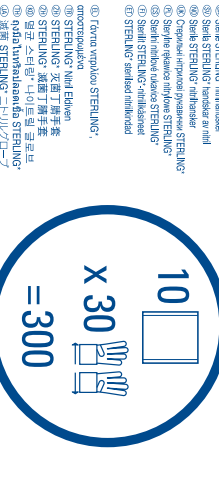
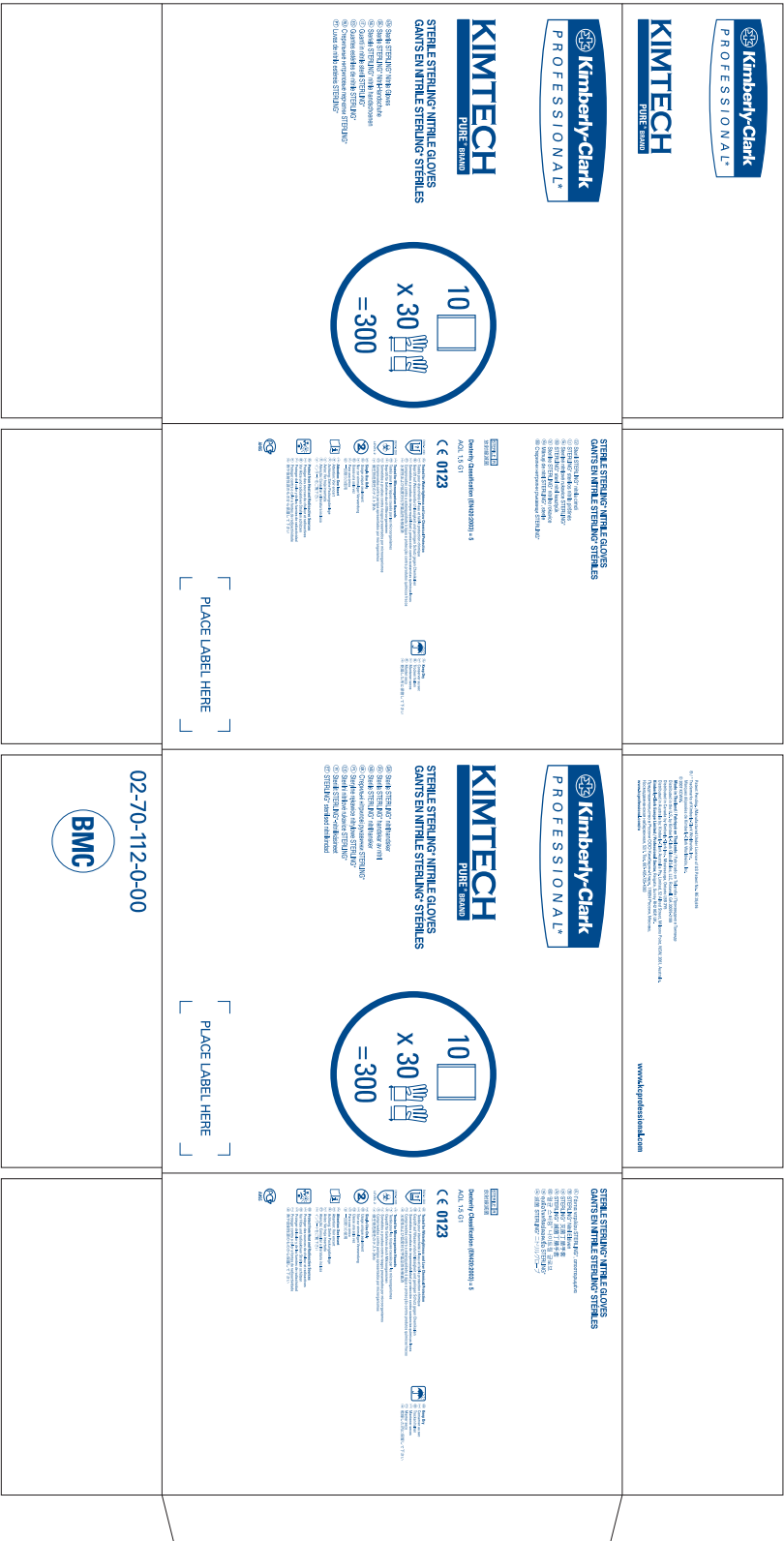
02-70-112-0-00

L1

W2

L3

W4



NOTE: Must comply with Kimberly-Clark Master Manufacturing Specification

Matthews

BRAND SOLUTIONS

FOR ALL ART REQUESTS PLEASE E-MAIL -
kcpnateam@matthewsbrandsolutions.co.uk
FOR ALL PLATE REQUESTS PLEASE E-MAIL -
pittsburghart@matw.com

Dimensions: 13.33 x 10.18 x 14.197

Mill: OEM Thailand

Dieline:

Flute: B/C

SUBSTRATE : Natural Kraft

COLORS: PMS-288 Blue

September 21, 2009 • 098396MBS SY

V1 07/21 SY



SAFESKIN MEDICAL & SCIENTIFIC (TH) LTD

DOSE SETTING VD Max STUDY TO ISO 11137-PART 2:2006

**“STERILIZATION OF HEALTHCARE PRODUCTS RADIATION
ESTABLISHING THE STERILIZATION PART 2:2006”**

**KIMTECH PURE * G3/G5 STERILE STERLING
NITRILE GLOVES**

REPORT NO. 0907371

JUNE - JULY 2009

Report Prepared By: Shafiqah 21/6/09 Microbiologist

Report Reviewed By: [Signature] 21/07/09 QA Manager



SUMMARY

This study was undertaken in accordance with Method VD max²⁵ of “Sterilization of healthcare products – Radiation Part 2 – Establishing the sterilization dose 11137-2:2006. The study was to substantiate a Sterilization dose of 25kGy. 3 batches of Kimtech Pure * G3/G5 Sterling Sterile Nitrile Gloves were assayed for bioburden levels. The overall average for the batch tested was 13.43 /unit sample. No single batch was shown to be more than twice this overall average and therefore this overall average was used to calculate the sub process verification dose.

With reference to Table 9 of the ISO 11137 – 2:2006 document, the nearest value listed equal to or greater than the bioburden level is 14 CFU. Therefore the sub- process dose required for the sterility assurance level of 10^{-1} is 7.5kGy +/- 10% (6.8 kGy – 8.2 kGy).

Therefore 10 units were irradiated at this dose and subsequently individually tested for sterility. After the full incubation period all tests gave a negative result, therefore statistical verification for the sub process dose is accepted.

In conclusion, a dose of 25kGy will provide a sterility assurance level of 10^{-6} .

Complete Dose Setting Study available on demand

Test Method for Analyzing Liquid Particle Counts

This test method is used to analyze the mobile particle contaminants from cleanroom gloves.

1. Scope

- 1.1. The test method covers the average particulate contamination found on gloves designated for cleanroom applicability.
- 1.2. The average contaminant concentration will be reported in particles per cm^2 in two ways:
 - 1.2.1. By size grouping, 0.5 to 1.0 microns, 1.0 to 2.0 microns, 2.0 to 5.0 microns, 5.0 to 10.0 microns, 10.0 to 20.0 microns, greater than 20.0 microns, and a total particle count greater than 0.5 microns.
 - 1.2.2. Statistical analysis of each grouping consisting of Minimum Value, Maximum Value, Standard Deviation, and Average Value, for each group of individual gloves.
- 1.3. The safe and proper use of gloves is beyond the scope of this test method.
- 1.4. This test method does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this Test Method to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

- 2.1. IEST-RP-CC005.3 Recommended Practice for Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments
- 2.2. Work Instruction

3. Apparatus

- 3.1. Analytical Balance, capable of readability and repeatability to 0.1 mg
- 3.2. Particle Measuring Systems CLS-900 Liquid Particle Counting System
- 3.3. 2000 mL glass beaker or 1000mL glass conical flask
- 3.4. Stainless Steel Forceps, 10" length
- 3.5. 250 ml Volumetric Flask
- 3.6. 500 ml Volumetric Flask
- 3.7. High Purity Deionized Water System, capable of producing 18.2 MOhm quality water
- 3.8. Point of Use Filter, 0.2 micron size
- 3.9. Orbital Shaker, $\frac{3}{4}$ " orbit, capable of 200 rpm
- 3.10. Circular Die, 1.5 inch diameter, calibrated

4. Procedure

4.1. Test Preparation

- 4.1.1. Prior to extraction, all Erlenmeyer flasks will be cleaned no less than five times with high purity deionized water filtered to 0.2 microns at point of use.
- 4.1.2. All related equipment (forceps, volumetric flasks, etc.) must be rinsed with high purity deionized water prior to use.

4.2. Extraction

- 4.2.1. Randomly pull a glove from the package.
- 4.2.2. Place glove finger-first into the one liter Erlenmeyer flask and hold open by cuff using the rinsed forceps.
- 4.2.3. Empty into the inside of the glove 500 ml high purity filtered deionized water.
- 4.2.4. Allow the glove to settle into the Erlenmeyer flask.
- 4.2.5. Place an additional 250 ml high purity filtered deionized water over the glove within the Erlenmeyer flask.
- 4.2.6. Allow the Erlenmeyer flask with glove to agitate on the shaker for 10 minutes $\pm$ 10 seconds at a rate of 150 rpm $\pm$ 10 rpm.
- 4.2.7. Using clean tongs, immediately remove the glove from the container. Drain any trapped liquid into the beaker by manipulating the fingers on the glove, with the tongs
- 4.2.8. Dispose of the glove.
- 4.2.9. Repeat the extraction two additional times to complete the set.
- 4.2.10. Prepare a process blank, using all the steps in section 4.2, without placing the glove in the Erlenmeyer flask.

4.3. Measurement

4.3.1. Follow the Work Instruction for the Liquid Particle Counter for analyzing the solutions.

4.4. Glove Surface Area

4.4.1. Pull three gloves from the production package and weigh to the nearest 0.1 mg.

4.4.2. Record as A.

4.4.3. Cut the 3 gloves with square die (5X5 cm.) by wheel cutter at palm. This will give you six cut-out sections.

4.4.4. Weight the six cut-out sections. Record this as B.

4.4.5. Calculate the surface area of the glove using the following equation :

$$\frac{A \times 5 \times 5 \times 4}{B}$$

5. Calculations

5.1. Calculate counts/cm² by channel size using the following equation:

$$\frac{(\text{Sample (counts/mL)} - \text{Blank (Counts/mL)}) \times \text{Extraction volume (mL)} \times \text{DF}}{\text{Surface area (in cm}^2\text{)}}$$

5.2. Total Counts/cm² : = $\sum$ *AllChannelSizes*

6. Reporting

6.1. The final report should include the Lot Number, Batch number, Product Description, Part Number, and any other pertinent information about the sample, as well as the final calculated counts/cm² by channel size and a total counts/cm² greater than 0.5 microns.

6.2. Statistics will be calculated and reported on sample sizes greater than three.

Test Method for Analyzing Extractables

This test method is used to analyze the soluble ionic extractable contaminants from cleanroom gloves.

1. Scope

- 1.1. The test method covers the average ionic contamination found on gloves designated for cleanroom applicability.
- 1.2. The average contaminant concentration will be reported in one of two ways:
 - 1.2.1. Micrograms of ionic contaminant per gram of glove weight (ug/g), also described as ppm.
 - 1.2.2. Micrograms of ionic contaminant per square centimeter of glove area (ug/cm²)
- 1.3. This test method does not cover contaminants that are insoluble in water, or organic macromolecules.
- 1.4. The safe and proper use of gloves is beyond the scope of this test method.
- 1.5. This test method does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this Test Method to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

- 2.1. IEST-RP-CC005.2 Recommended Practice for Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments.
- 2.2. Work Instruction WI 10-05-26, Work Instruction for Performing Ion Chromatography Analysis of Gloves

3. Apparatus

- 3.1. Analytical Balance, capable of readability and repeatability to 0.1 mg
- 3.2. Ion Chromatograph
- 3.3. Extraction Containers, 1 liter capacity, HDPE with screw type lids
- 3.4. Stainless Steel Forceps, 10" length
- 3.5. 500 ml Volumetric Flask
- 3.6. High Purity Deionized Water System, capable of producing 18.0 MOhm quality water
- 3.7. Point of Use Filter, 0.1 micron size
- 3.8. Circular Die, 1.5 inch diameter, calibrated

4. Procedure

4.1. Test Preparation

- 4.1.1. Prior to extraction, all extraction containers will be cleaned using high purity deionized water high purity deionized water filtered to 0.2 microns at point of use.
- 4.1.2. All related equipment (forceps, volumetric flasks, etc.) must be rinsed with high purity de-ionized water prior to use.

4.2. Extraction

- 4.2.1. Randomly pull a glove from the package.
- 4.2.2. Place glove finger-first into the one liter Erlenmeyer flask and hold open by cuff using the rinsed forceps.
- 4.3. Empty into the inside of the glove approximately 250 ml high purity filtered deionized water.
- 4.4. Allow the glove to settle into the extraction container.
- 4.5. Pour remaining 250 ml high purity filtered deionized water over the glove within the extraction container.
- 4.6. Place the lid upon the container and seal tightly.
- 4.7. Gently swirl the container to ensure that all surfaces of the glove are wetted.
- 4.8. Allow the glove to extract in the deionized water for at least 10 minutes, but no longer than 11 minutes.
- 4.9. Remove the glove by the fingers, allowing most of the water trapped in the fingers to drain back in to the extraction container.
- 4.10. Dispose of the glove.
- 4.11. Repeat extraction two additional times to complete the set.
- 4.12. Prepare a sample blank, using all the steps in section 2, without placing the glove in the extraction container.

4.13. Measurement

4.13.1. Follow the guidelines for the Ion Chromatograph for analyzing aqueous solutions.

4.14. Glove weight and surface area

4.14.1. Pull three gloves from the production package and weigh to the nearest 0.1 mg.

4.14.2. Record as A.

4.14.3. Cut the 3 gloves with square die (5X5 cm.) by wheel cutter at palm. This will give you six cut-out sections.

4.14.4. Weight the six cut-out sections. Record this as B.

4.14.5. Calculate the surface area of the glove using the following equation :

$$\text{Surface area} = \frac{A \times 5 \times 5 \times 4}{B}$$

5. Calculations

5.1. Once the data output from the Chromatograph has been reviewed for errors, calculate the following:

$$5.1.1. \text{ ug/g (ppm) contamination: } = \frac{(\text{AnalyteConc.}) * (500\text{ml})}{\text{GloveWeight}}$$

$$5.1.2. \text{ ug/cm}^2 \text{ contamination: } = \frac{(\text{AnalyteConc.}) * (500\text{ml})}{\text{SurfaceArea}}$$

6. Reporting

6.1. The final report should include the Lot number, Batch number, Product description, Part number, and any other pertinent information about the sample, as well as the final calculated contaminant concentration in ug/g and ug/cm².