Kimberly-Clark PROFESSIONAL*

# KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves

## Engineered for Protection. Designed for Comfort.

DATA PACK



KIMTECH PURE* BRAND

Kimberly-Clark PROFESSIONAL*

# 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
- Walleted & 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.

Reduce Today Respect Tomorrow*

EN374-2:2003

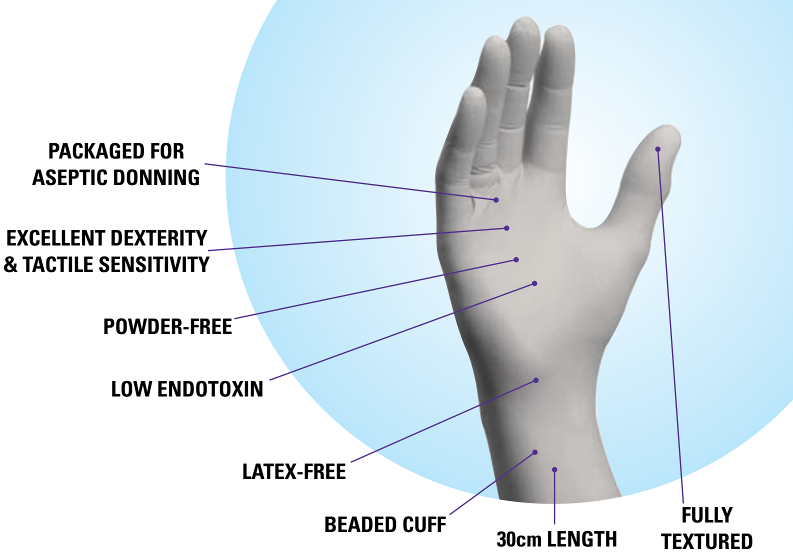
LEVEL 2

EN374-1:2003

CE 0123

KIMTECH PURE* BRAND

Kimberly-Clark PROFESSIONAL*




# 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

**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% | ASTM D 412 and ASTM D 573 |
| - After Accelerated Aging | 38 MPa / 550% | |
| **Dimensional** | **Measured Point** / **mm** | |
| - Thickness | Middle Finger 0.10 | ASTM D 3767 and D 6319 |
| | Palm 0.08 | |
| | Cuff 0.07 | |
| **Palm Widths** | | |
| - Width (mm) | 6 / 6.5 / 7 / 7.5 / 8 / 8.5 / 9 / 10 | ASTM D 3767 / D 6319 and EN420 |
| | 80 / 87 / 94 / 98 / 109 / 114 / 120 / 128 | |
| **Particles (maximum)** | | |
| - Per cm$^2$ > 0.5 micron | 1500 | IEST-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 | 30x |
| 6.5 | 11822 | |
| 7 | 11823 | |
| 7.5 | 11824 | |
| 8 | 11825 | |
| 8.5 | 11826 | = 300 |
| 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**

Reduce Today Respect Tomorrow


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


**www.contaminomics.com**

Contaminomics

Kimberly-Clark PROFESSIONAL*

# 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)

# 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 Minor | Visual Defects Major | Elongation (%) Pre Aging | Tensile (MPa) 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/cm² |
|---|---|---|---|---|
| 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/cm² | <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 Zn |
|---|---|---|---|---|---|---|
| µg/g glove | 1.1 | 0.9 | 1.6 | <0.25 | 9.9 | 4.1 |
| µg/cm² | 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



Review By : Sonni B.
( QA Executive - SSMT )

SA-FORM01193/2

# CERTIFICATE OF IRRADIATION

Number: **MA** 0025517

SAF005

SAFESKIN MEDICAL & SCIENTIFIC (THAILAND) LTD
200 Moo 8, KANJANAVANICH ROAD
TAMBOL PRIK
AMPHUR SADAO, 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<br>M209120023 | KIMTECH Pure* G3, Sterile Sterling * Nitrile Gloves, 12" Hand Specific Pairs | 546 | See below |
| | Total | 546 | Last page 1 of 1 |

| 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 |

IRRADIATION DATE:
03/12/2009

DOSE REQUIRED:
25.0-50.0 kGy

ACTUAL DOSE RECEIVED:
MIN:26.3 kGy
MAX:36.1 kGy

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

04/12/09

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

# Kimberly-Clark Corporation

## 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

Larry Kludt
Global Regulatory Affairs Manager
Kimberly-Clark Europe

Kimberly-Clark PROFESSIONAL*

06-70-113-0-00

Kimberly-Clark PROFESSIONAL*

KIMTECH PURE* BRAND

## G3 STERILE STERLING* NITRILE GLOVES
## GANTS EN NITRILE STERLING* G3 STÉRILES

EN374-1: 2003

(EN) **Tested for Watertightness and Low Chemical Protection**
(FR) **Testés pour étanchéité à l'eau et faible protection chimique**
(DE) Geprüft auf Wasserfestigkeit und geringen Schutz gegen Chemikalien
(ES) Sometidos a pruebas de impermeabilidad y protección contra sustancias químicas leves
(PT) Comprovadas contra a estanqueidade à água e protecção contra produtos químicos fracos
(JA) 水密性および低度対化学薬品性を検査済

EN374-2: 2003

LEVEL 2

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

(EN) **Attention: See Insert**
(FR) **Attention: Voir encart**
(DE) Achtung: Siehe Packungsbeilage
(ES) Aviso: Ver hoja insertada
(PT) Atenção: Consultar a literatura inclusa
(JA) インサートをご覧下さい

(EN) **Keep Dry**
(FR) **Conserver au sec**
(DE) Trocken halten
(ES) Mantener secos
(PT) Manter seco
(JA) 乾燥した所に保管して下さい

(EN) **Protect from Heat and Radioactive Sources**
(FR) **Protéger des sources de chaleur et radioactives**
(DE) Vor Hitze und radioaktiven Strahlen schützen
(ES) Proteger del calor y de las fuentes de radiactividad
(PT) Proteger contra o calor e fontes de radioactividade
(JA) 熱や放射性源のものから保護して下さい

Patent Pending. / Manufactured Under License of US Patent No.: RE 35,616

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Kimberly-Clark Europe Limited / Professional Sector, Reigate, Surrey RH2 9QP, UK.
www.kcprofessional.com
Представительство в России ООО Кимберли-Кларк. 115054 Россия, Москва,
Космодамианская набережная, 52/1. Тел. 007-495-725-4383
www.kcprofessional.com/ru

| | | REF |
|---|---|---|
| ☐ | 6.0 | 11821 |
| ☐ | 6.5 | 11822 |
| ☐ | 7.0 | 11823 |
| ☐ | 7.5 | 11824 |
| ☐ | 8.0 | 11825 |
| ☐ | 8.5 | 11826 |
| ☐ | 9.0 | 11827 |
| ☐ | 10.0 | 11828 |

1

CE 0123
EN420

STERILE R
放射線滅菌
AQL 1.5 G1

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

V1 07/21 SY

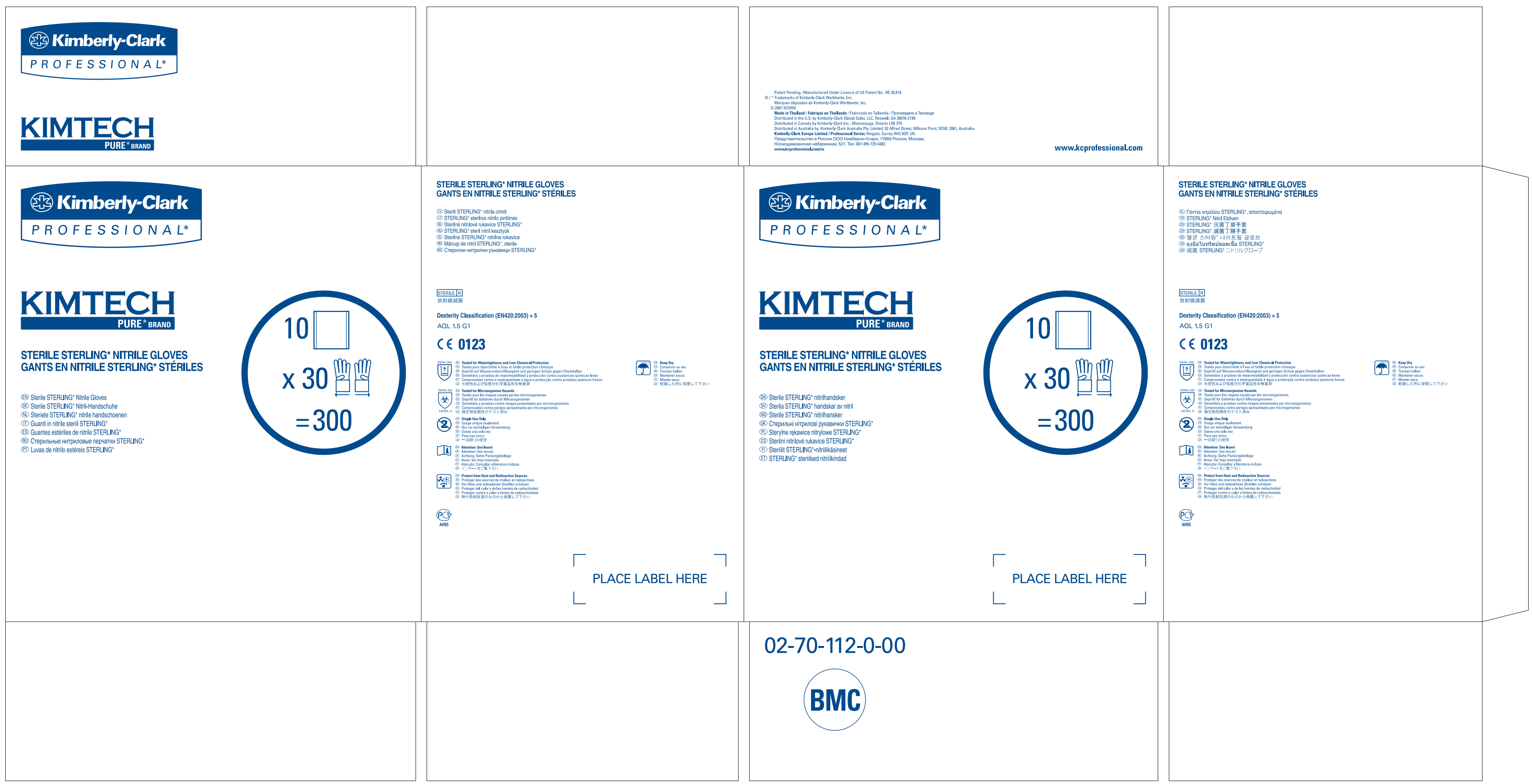
**Dimensions:** 6 x 12
**Mill:** OEM Thailand
**Dieline:** STB003-1
**Flute:**

August 26, 2009 • 096880MBS MG

**SUBSTRATE :** PET/PE Film
COLORS: PMS 267
Overall Lacquer Coverage

Kimberly-Clark PROFESSIONAL*

# 02-70-112-0-00




Kimberly-Clark PROFESSIONAL*

KIMTECH PURE* BRAND

STERILE STERLING* NITRILE GLOVES
GANTS EN NITRILE STERLING* STÉRILES

(EN) Sterile STERLING* Nitrile Gloves
(DE) Sterile STERLING* Nitril-Handschuhe
(NL) Steriele STERLING* nitrile handschoenen
(IT) Guanti in nitrile sterili STERLING*
(ES) Guantes estériles de nitrile STERLING*
(RU) Стерильные нитриловые перчатки STERLING*
(PT) Luvas de nitrilo estéreis STERLING*

(LV) Sterili STERLING* nitrila cimdi
(LT) STERLING* sterilios nitrilo pirštinės
(SK) Sterilné nitrilové rukavice STERLING*
(HU) STERLING* steril nitril kesztyűk
(SL) Sterilne STERLING* nitrilne rokavice
(RO) Mănuşi de nitril STERLING*, sterile
(BG) Стерилни нитрилни ръкавици STERLING*

(DA) Sterile STERLING* nitrilhandsker
(SV) Sterila STERLING* handskar av nitril
(NO) Sterile STERLING* nitrilhansker
(UK) Стерильні нітрилові рукавички STERLING*
(PL) Sterylne rękawice nitrylowe STERLING*
(CS) Sterilní nitrilové rukavice STERLING*
(FI) Steriilit STERLING*-nitriilikäsineet
(ET) STERLING* steriilsed nitriilkindad

(EL) Γάντια νιτριλίου STERLING*, αποστειρωμένα
(TR) STERLING* Nitril Eldiven
(ZH) STERLING* 灭菌丁腈手套
(ZH) STERLING* 滅菌丁腈手套
(KO) 멸균 스터링* 나이트릴 글로브
(TH) ถุงมือไนทริลปลอดเชื้อ STERLING*
(JA) 滅菌 STERLING* ニトリルグローブ

10
x 30
=300

STERILE R
放射線滅菌

**Dexterity Classification (EN420:2003) = 5**

AQL 1.5 G1

CE 0123

АИ95

Patent Pending. /Manufactured Under Licence of US Patent No.: RE 35,616

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EN374-1; 2003

(EN) **Tested for Watertightness and Low Chemical Protection**
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EN374-2; 2003 LEVEL 2

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(FR) Testés pour les risques causés par les microorganismes
(DE) Geprüft für Gefahren durch Mikroorganismen
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(PT) Comprovadas contra perigos apresentados por microrganismos
(JA) 微生物危険性のテスト済み

(EN) **Single Use Only**
(FR) Usage unique seulement
(DE) Nur zur einmaligen Verwendung
(ES) Úsese una sola vez
(PT) Para uso único
(JA) 一回限りの使用

(EN) **Keep Dry**
(FR) Conserver au sec
(DE) Trocken halten
(ES) Mantener secos
(PT) Manter seco
(JA) 乾燥した所に保管して下さい

(EN) **Protect from Heat and Radioactive Sources**
(FR) Protéger des sources de chaleur et radioactives
(DE) Vor Hitze und radioaktiven Strahlen schützen
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(EN) **Attention: See Insert**
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NOTE: Must comply with Kimberly-Clark Master Manufacturing Specification

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**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: ..................................... 21/07/09 Microbiologist

Report Reviewed By: ..................................... 21/07/09 QA Manager

# SUMMARY

This study was undertaken in accordance with Method VD max [25] 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 was13.43 /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, ¾" 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 ± 10 seconds at a rate of 150 rpm ± 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/cm$^2$ by channel size using the following equation:

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

5.2. Total Counts/cm$^2$ : $= \sum AllChannelSizes$

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/cm$^2$ by channel size and a total counts/cm$^2$ 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 ($ug/cm^2$)
   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. ug/g (ppm) contamination: $= \dfrac{(AnalyteConc.) * (500ml)}{GloveWeight}$

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

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 $ug/cm^2$.