Kimberly-Clark PROFESSIONAL*

KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves

Engineered for Protection. Designed for Comfort.

DATA PACK

KIMTECH PURE* BRAND

Kimberly-Clark PROFESSIONAL*

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KIMTECH* BRAND

www.kimtech.com
800-255-6401

KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves

Product Information

Code	Description	Size
11821	KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves	6
11822	KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves	6.5
11823	KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves	7
11824	KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves	7.5
11825	KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves	8
11826	KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves	8.5
11827	KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves	9
11828	KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves	10

Material: Synthetic nitrile polymer (Acrylonitrile Butadiene). Contains no natural rubber latex. Silicone-free.
Design: 12" in length, hand-specific, beaded cuff, with textured palm and palm side on fingertips.
Sterilization: Gamma irradiation. Validated to a Sterility Assurance Level (SAL) of 10^{-6} according to ANSI/AAMI/ISO 11137.
Packaging: 1 pair/poly pouch, 30 pairs/double bag, 10 double bags (300 pairs/case)

Physical Properties

Characteristics	Value	Test Method
Freedom from holes	1.5 AQL[1]	ASTM D 5151

1 AQL as defined per ISO 2859-1 for sampling by attributes

Tensile Properties	Tensile Strength	Ultimate Elongation	Test Method
Before Aging	42 MPa, nominal	650%, nominal	ASTM D 412 and D 573
After Accelerated Aging	38 MPa, nominal	550%, nominal	

Dimensional	Measured Point	mm	mil	Test Method
Nominal Thickness	Middle finger	0.10	3.90	ASTM D 3767 and D 6319
	Palm	0.08	3.10	
	Cuff	0.07	2.80	
Nominal Length	305mm/12 inches			

Palm Widths	6	6.5	7	7.5	8	8.5	9	10	Test Method
Nominal Width (mm)	80	87	94	98	109	114	120	128	ASTM D 3767 and D 6319

Particles (maximum)		
Per $cm^2 \geq 0.5$ micron	1200	IEST-RP-CC005

Endotoxin (maximum)		
Endotoxin Units/pair	20	LAL Kinetic Turbidimetric Method

KIMTECH PURE* BRAND

CERTIFICATE OF ANALYSIS

Product Description : KIMTECH PURE* G3 Sterile STERLING Nitrile Gloves , 12" Hand Specific
Catalog Numbers : 11821, 11822, 11823, 11824, 11825, 11826, 11827, 11828

Lot # : 970810
Batches : SM02132XX to SM02432XX
Total Cases per Lot : 612
Date of Manufacture : Aug-10
Expiration Date : 2013 -07

Physical Test Data**

			Visual Defects		Elongation (%)	Tensile (MPa)
	Watertight	Dimensions	Minor	Major	Pre Aging	Pre Aging
Sample Size :	990	360	990	990	140	140
AQL Level :	1.5	2.5	4.0	2.5	2.5	2.5
Failures Allowed per AQL :	24	18	57	39	7	7
Failures :	4	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept
				Averages:	575	35.8

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	182	634	120	417
1.0 - 2.0	23	83	16	47
2.0 - 5.0	4	25	6	13
5.0 - 10.0	0	5	1	1
10.0 - 20.0	0	1	0	0
>20	0	0	0	0
Total per Sample	216	746	136	479

Test Method : IEST-RP-CC005.3

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	16.8	<2.5	<2.5	6.4	<5	2.7
µg/cm²	<0.003	0.078	<0.016	<0.016	0.030	<0.031	0.014

	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	1.1	1.7	0.3	9.6	2.4
µg/cm²	0.005	0.005	0.008	0.002	0.045	0.011

Test Method : IEST-RP-CC005.3

Endotoxin Data**

Test Result:	0.400	Endotoxin Units/ device (pair)
Specification:	< 20	Endotoxin Units/ device (pair)

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

**Testing performed at final quality inspection gate prior to sterilization.

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

CERTIFICATE OF IRRADIATION

Number: **MA** 0029421

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: 4027001987
Date Rec'd: 02/09/10
Date 06/09/10

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
M1SAF0050021 M210090041	KIMTECH Pure* G3, Sterile Sterling * Nitrile Gloves, 12" Hand Specific Pairs	576	
	Total	576	Last page 1 of 1

CAT NO	MFG LOT/BATCH NO	QTY
11821	970810/SM02192XX	36
11822	970810/SM02142XX	9
11822	970810/SM02152XX	27
11822	970810/SM02152XX	30
11822	970810/SM02192XX	6
11823	970810/SM02152XX	15
11823	970810/SM02172XX	21
11823	970810/SM02172XX	32
11823	970810/SM02172XX	4
11823	970810/SM02172XX	36
11824	970810/SM02142XX	36
11824	970810/SM02142XX	24
11824	970810/SM02152XX	19
11824	970810/SM02152XX	12
11824	970810/SM02152XX	36
11824	970810/SM02162XX	18
11824	970810/SM02182XX	17
11824	970810/SM02182XX	18
11825	970810/SM02162XX	36
11825	970810/SM02162XX	36
11826	970810/SM02152XX	24
11826	970810/SM02182XX	32
11826	970810/SM02192XX	12
11826	970810/SM02192XX	4
11827	970810/SM02132XX	28
11827	970810/SM02172XX	8

IRRADIATION DATE:
03/09/2010

DOSE REQUIRED:
25 - 50 kGy

ACTUAL DOSE RECEIVED:
MIN:26.7 kGy
MAX:36.8 kGy

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

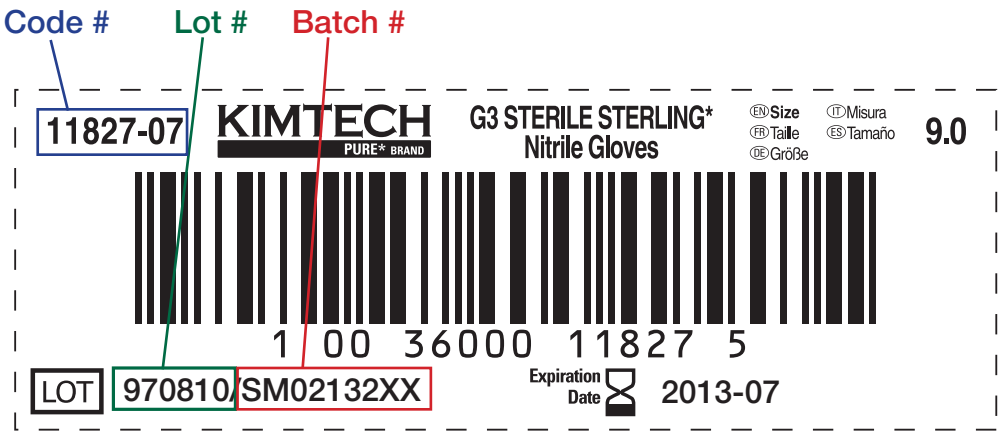
02/09/10

TAI ENG TIING
QA Officer
Isotron (Malaysia) Sdn. Bhd

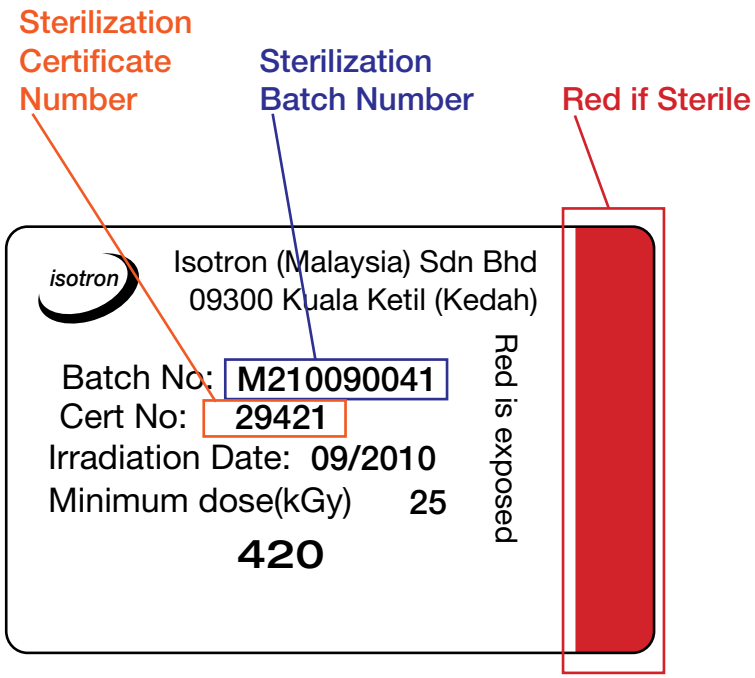
Authorised Signature:

For and on behalf of **ISOTRON MALAYSIA** Sdn Bhd

Package Label


Code #
Lot #
Batch #
11827-07
KIMTECH
PURE* BRAND
G3 STERILE STERLING*
Nitrile Gloves
EN Size
FR Taille
DE Größe
IT Misura
ES Tamaño
9.0
1 00 36000 11827 5
LOT
970810
SM02132XX
Expiration Date
2013-07

Case Label



Sterilization Label


STERILE R
放射線滅菌
AQL 1.5 G1
1
CE 0123
EN420
Kimberly-Clark
PROFESSIONAL*
KIMTECH
PURE* BRAND
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
G3 STERILE STERLING* NITRILE GLOVES
GANTS EN NITRILE STERLING* G3 STÉRILES
Tested for Watertightness and Low Chemical Protection
Tested pour étanchéité à l'eau et table protection chimique
Tested for Microorganism Hazards
Testés pour les risques causés par les microorganismes
Attention: See Insert
Attention: Voir encart
Keep Dry
Conserver au sec
Protect from Heat and Radioactive Sources
Protéger des sources de chaleur et radioactives
Patent Pending. / Manufactured Under License of US Patent No. RE 35,616
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COLOR GREY = Trademark of ACCW © 2007 ACCW.
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Kimberly-Clark Europe Limited / Professional Sector, Reigate, Surrey RH2 9QP, UK.
www.kcprofessional.com
Представительство в России ООО Кимберли-Кларк, 119334 Россия, Москва,
Ленинский проспект, 32/1, Тел. 007-495-725-4383
www.kcprofessional.com/ru
06-70-113-0-00

Pouch Label

ISOTRON MALAYSIA SDN BHD

(Company No.: 512058-V)

STANDARDS MALAYSIA ACCREDITED LABORATORY
MS ISO/IEC 17025
TESTING
SAMM NO : 309

ANAB BSI
ISO 9001 : 2008
CERT NO : FS60510

BSI UKAS QUALITY MANAGEMENT 003
ISO 13485 : 2003
CERT NO : MD 75461

Customer: SAFESKIN MEDICAL & SCIENTIFIC
200 Moo 8, Kanchanavanich Road
Tombol Prik, Amphur Sadao, Songkhla
90120 Thailand.

PRODUCT STERILITY TEST CERTIFICATE OF ANALYSIS

Certificate No.: 804
Purchase Order No.: 4561072439
Isotron sample Log No.: 1236
Isotron Batch No.: M210121007
Date Processed: 08/12/10 & 10/12/10
Product Name: Kimtech Pure* G3 Sterile Sterling Gloves Hand Specific 12"Pair Packed (KTPG3 STRLNG STERILE)
Product Lot No.: SM02862XX
No. of Samples: 10 pairs
Date Samples Received: 22/11/10
Date Tested: 15/12/10
Date Incubation Completed: 29/12/10

Results:

Item Description	Test Results	Reference Standard
Product Sterility Test in Tryptone Soya Broth	All Negative	ISO 11737-2

Incubation condition: 30 ± 2°C

Comments: Volume of media used: 400ml

Certified By: _____ **Date:** 30/12/10

JAYANTHIMALA . A
QA Manager
Isotron (Malaysia) Sdn. Bhd.

FM-127 Rev.4; 2nd March 2007

SAFESKIN
Medical & Scientific (Thailand) Ltd.

STERILITY TEST REPORT

KIMTECH PURE* G3 STERILE STERLING

GLOVES HAND SPECIFIC 12" PAIR PACKED (KTPG3 STRLNG STERILE)

TEST REPORT NO. 1012655

NOVEMBER – DECEMBER 2010

Report Prepared By: ..... 30/12/10 Microbiologist

Report Approved By: ..... 30/12/10 ..... QA Manager

JAYANTHIMALA . A
QA Manager
Isotron (Malaysia) Sdn. Bhd.

CONTENTS

INTRODUCTION

Sterility is an absolute term, but the assurance that any given item is sterile is a probability function. The sterility assurance level (SAL) is defined as the probability of any given unit being non-sterile after exposure to a validated sterilization process.

The bioburden estimation of the products was done following method 1 by Safeskin Medical & Scientific (Thailand) and the dose verification was advised by customer as 7.5 kGy +/- 10 %.

Dose was delivered as follows:

Min 6.9 kGy **Max 7.2 kGy**

10 samples were irradiated and test of sterility was performed on all 10 samples.

STERILITY TESTING

Sample

Kimtech Pure *G3 Sterile Sterling Gloves, Hand Specific, 12" Pair Packed. (KTPG3 Strlng Sterile)

Product Lot Number SM02862XX

Method

References: USP 33<71> 2010
: ISO 11137 – 2:2006 Sterilization of Healthcare Products –Radiation Part 2 – 2006 Establishing the Sterilization Dose
: ISO 11737- 2: 2009 Sterilization of medical devices –Microbiological Methods Part 2: Tests of sterility performed in the validation of a Sterilization process

All sterility testing was carried out under the protection of laminar flow in a clean room operated in accordance with LWI 51 (Test Of Sterility – Gamma Processing) and monitored in accordance with LWI 20 (Cleaning and Environmental Monitoring of Clean Room) supplemented by the placement of settle plates and contact plates.

The whole of the sample were aseptically transferred into a bottle containing 400 ml of Tryptone Soya Broth to completely immerse the sample. The samples were incubated at 30°C +/-2°C for 14 days. The samples are inspected daily for signs of microbial growth.

Results

Please see Test of Sterility Result Forms.

Zero positive results were noted after a full incubation period of 14 days.

TEST FOR STERILITY RESULT FORM

Customer Name: Safeskin Medical & Scientific (Thailand) Ltd.
200 Moo 8,Kanchanavanich Road, Tambol Prik,
Amphur Sadao,Songkhla 90120, Thailand

Test Number: 804

Test Product: Kimtech Pure*G3 Sterile Sterling Gloves, Hand Specific, 12" Pair Packed. (KTPG3 Strlng Sterile)

Product Lot Number: SM02862XX

Date Samples Received : 22.11.2010

Date Test Carried Out: 15.12.2010

Date Test Complete: 29.12.2010

Signature: .....

10 samples were tested for sterility.

Growth Promotion : Test media meets the USP 33 <71>

Tryptone Soy Broth (2615 TSB 01/01/11)	
Test Organism	Result
***Bacillus spizizenii* ATCC 6633**	Growth
***Candida albicans* ATCC 10231**	Growth
***Aspergillus brasiliensis* ATCC 16404**	Growth
Negative Control	No Growth

TSB Mfr. Batch No: VM187059

TSB Batch No: 2615TSB01/01/10

Negative control: All clear

Positive control: Growth: *S.aureus, B.spizizenii, Ps aeruginosa, C.albican, A.brasiliensi*

14 days at 28 ^{0}C - 32^{0}C

Daily check on 10 items **TEST PASSED** ☑ **FAILED** ☐

Result: All clear **Signature:** .....

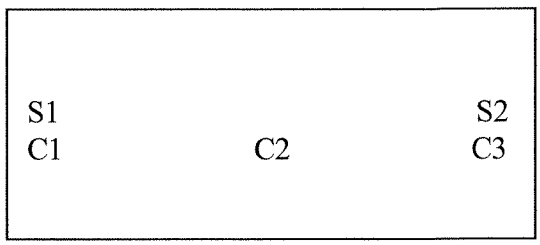
Day	Number Negative	Number Positive	Date	Initials
1	10	Nil	16.12.10	
2	10	Nil	17.12.10	
3	10	Nil	18.12.10	
4	10	Nil	19.12.10	
5	10	Nil	20.12.10	
6	10	Nil	21.12.10	
7	10	Nil	22.12.10	
8	10	Nil	23.12.10	
9	10	Nil	24.12.10	
10	10	Nil	25.12.10	
11	10	Nil	26.12.10	
12	10	Nil	27.12.10	
13	10	Nil	28.12.10	
14	10	Nil	29.12.10	

MEDIA FORMULAE

Tryptone Soya Agar (Merck)	**gm/L**
Tryptone Soya Agar	40
pH 7.3 +/- 0.2	

Tryptone Soya Broth (Merck)	**gm/L**
Tryptone Soya Broth	30
pH 7.3 +/- 0.2	

ENVIRONMENTAL MONITORING DATA SHEET



LAMINAR FLOW CABINET

Key :
S = settle plates
C = contact plates

Date exposed : 15.12.2010
Date read : 22.12.2010
Total : 0 CFU

	TOTAL CFU
Date	22.12.2010
S1	0
S2	0

	TOTAL CFU
	22.12.2010
C1	0
C2	0
C3	0

Analyst : 20/12/10

CERTIFICATE OF IRRADIATION Number: MA 0030997 00

SAF005

SAFESKIN MEDICAL & SCIENTIFIC
(THAILAND) LTD
ATTN: FON @ SAIYUD. THANMAJARO
200 MOO 8, KANJANAVANICH ROAD
TAMBOL PRIK, AMPHUR SADAO
SONGKHLA- THAILAND

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: PO 4561072439
Date Rec'd: 15/12/10
Date 15/12/10

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
M1SAF0051001	SAMPLE IRRADIATION @ 0.1 - 15.0 kGy	1	ISOTRON BATCH NO: M210121007 . DESCRIPTION: KIMTECH PURE*G3 STERILE STERLING GLOVES,HAND SPECIFIC,12" PAIR PACKED (KTPG3 STRLNG STERILE) . LOT NO:SM02B62XX . IRRADIATION DATE: 08/12/2010 & 10/12/2010 . DOSE REQUIRED: 7.5 kGy +/-10%(6.8 - 8.2 kGy) . ACTUAL DOSE RECEIVED: MIN:6.9 kGy MAX:7.2 kGy
	Total	1	Last Page 1 of 1

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

TAI ENG THING
QA Officer
Isotron (Malaysia) Sdn. Bhd.

Authorised Signature:

For and on behalf of **ISOTRON MALAYSIA** Sdn Bhd

STERILITY TEST REPORT 1012655

APPLICATION OF VERIFICATION DOSES

Reported by: 16/12/10
Tai Eng Thing
QA Officer

Approved by: 16/12/10
Jayanthimala A
QAM

Report number : 10-243-VD

Sample batch number : M210121007

Customer name : Safeskin Medical & Scientific (Thailand) Ltd.

A/C number : SAF002

Sample description : Kimtech Pure*G3 Sterile Sterling Gloves, Hand Specific, 12"Pair Packed (KTPG3 STRLNG STERILE)
Lot no.: SM02862XX

Microbiological dose setting methods described in ISO11137-2: 2006 require the irradiation of samples at a given dose within a range of +/- 10 %.

This exercise is to confirm that the doses applied to all samples throughout the package are within the specified range of 7.5 kGy ± 10%.

Dose values are obtained by reading calibrated ***Amber Perspex*** dosimeters placed among the samples as described in attachment 1. Dosimeters are distributed throughout the package to ensure that the positions of maximum and minimum doses are identified and that the absorbed doses in these positions can be recorded.

Samples are processed with key parameters of both the product and the total exposure time being recorded. After irradiation, dosimeters are recovered and the absorbed doses from each position from the samples are calculated and recorded. Detail results are recorded in attachment 2.

SUMMARY

The one carton sample were irradiated within the required dose range of 6.8 kGy to 8.2 kGy (7.5 kGy ± 10%) and actual dose received were 6.9 kGy to 7.2 kGy.

LOAD DESCRIPTION

Type of carton	:	Corrugated inner box
Carton dimension (mm) L X W X H	:	345 X 265 X 370
Weight of 1 carton (kg)	:	8.15
Density (g/cm^3)	:	0.24

PROCESSING INFORMATION

Average dose rate	:	1.9 kGy / h
Verification dose requested	:	7.5 kGy ± 10%
Minimum dose less 10% tolerance (rounded off to the upper 0.1 kGy)	:	6.8 kGy
Minimum exposure time (hh:mm)	:	3 hours 35 minutes
Maximum dose plus 10% tolerance (rounded off to the lower 0.1 kGy)	:	8.2 kGy
Maximum exposure time	:	4 hours 19 minutes
Exposure started on / at	:	08 / 12 / 10 at 12:40 and 10 / 12 / 10 at 18:45
Exposure was interrupted for	:	2 hours 15 minutes
Exposure finished on / at	:	08 / 12 / 10 at 13:45 and 11 / 12 / 10 at 00:05
Actual exposure time	:	3 hours 47 minutes

DOSIMETRY RESULTS SUMMARY

	Minimum dose	Maximum dose
Dose requested (kGy)	6.8	8.2
Actual dose received (kGy)	6.9	7.2

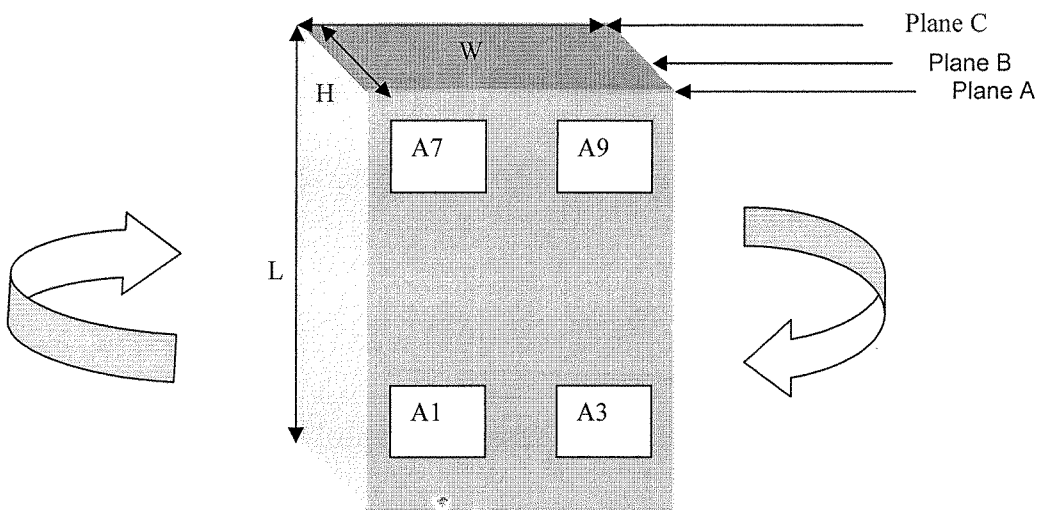
Reference : Attach detailed dosimetry report.

Attachment 1

EXPOSURE TO RADIATION

For irradiation, a carton is placed on a hanging cage. The rotation of the carton aims at obtaining doses within the narrowest possible range. The exposure time is calculated from the times when the cage start touching at the end unit of the TEKSI.

CARTON LOADING DIAGRAM ON TEKSI



Represents dosimeter location at each plane

VALIDATION DOSIMETRY

ISOTRON Malaysia Site

R&D dosimetry using Amber Perspex dosimeters Batch No.: 3042V
N.P.L. Certificate Number: 2009060186-1
Thermo Unicam UV1 Sectrophotometer serial number: 90903

Date: 09/12/2010
Customer Name: SAFESKIN
Product description:
Reference: 4561072439
Plant Batch Number and Date: M210121007

Number	Optical Density (OD)	Thickness (T)	OD/T	Dose (kGy)	Routine
A1	133	292	0.455	1.8	
A3	136	297	0.458	1.8	
A7	159	328	0.485	1.9	
A9	134	264	0.508	2.0	
B1	131	288	0.455	1.8	
B3	137	300	0.457	1.8	
B7	156	313	0.498	1.9	
B9	148	295	0.502	1.9	

Number	Optical Density (OD)	Thickness (T)	OD/T	Dose (kGy)	Routine

Signed: Rif Dated: 09/12/10

VALIDATION DOSIMETRY

ISOTRON Malaysia Site

R&D dosimetry using Amber Perspex dosimeters Batch No.: 3042V
N.P.L. Certificate Number: 2009060186-1
Thermo Unicam UV1 Sectrophotometer serial number: 90903

Date: 13/12/10
Customer Name: SAFESKIN
Product description:
Reference: 4561072439
Plant Batch Number and Date: M210121007

Number	Optical Density (OD)	Thickness (T)	OD/T	Dose (kGy)	Routine
A1	342	262	1.305	5.1	
A3	417	314	1.328	5.2	
A7	407	303	1.343	5.2	
A9	383	286	1.339	5.2	
B1	378	288	1.313	5.1	
B3	361	275	1.313	5.1	
B7	358	269	1.331	5.2	
B9	427	319	1.339	5.2	

Number	Optical Density (OD)	Thickness (T)	OD/T	Dose (kGy)	Routine

Signed: _____ Dated: 13/12/10

DOSE MAPPING REPORT
SAFESKIN MEDICAL & SCIENTIFIC (THAILAND) LTD.
FOR

KIMTECH Pure* G3, Sterile Sterling Nitrile Gloves -12" Hand Specific Pairs

Validation Report Number : 0.0358 Rev. 1

Summary of Performance Qualification:

Customer Name: **Safeskin Medical & Scientific (Thai) Ltd.**
Report Ref.: **0.0358**
Issue Date: **08.03.2011** Expiry Date: **08.03.2016**

Product Description: **KIMTECH Pure* G3 Sterile Sterling Nitrile Gloves - 12" Hand Specific Pairs**

Type of package: **Corugated Carton**

No of Packages/Irradiation Container: **16**

Dimensions of Package (mm): **345** x **265** x **370**

Method : **ASTM E 2303-03**

Reference Standard : **ISO 11137**

Dose Specification:

Minimum dose (kGy): 25.0
Maximum dose (kGy): 50.0

Requirement	Minimum specification	Maximum specification
Dose at DRef	30.8	45.4
Dwell time(s)	170	245
Number of Xs	38	55

Conclusion

The delivered dose in the product presentation illustrated on page 7 achieves the requested dose specification of 25.0 kGy minimum dose and 50.0 kGy maximum dose. In order to meet this specification during routine processing the recorded dose at Dref must be between 30.8 kGy and 45.4 kGy. This incorporates an estimation of uncertainty associated with the measurement system.

Authorisation

Position	Signature	Date
QA Officer		11/03/11
QAM		11/03/11

Note:
It is the responsibility of the customer to routinely provide product in the presentation and orientation outlined in this report.
This performance qualification validates the delivery of radiation doses only. Validation of the sterilisation effect and radiation induced material effects, if any, are not addressed by this qualification.

Product description: KIMTECH Pure* G3 Sterile Sterling Nitrile Gloves - 12" Hand Specific

Qualification data is obtained by placing red dosimeters in a defined pattern throughout an Isotron tote loaded with product.

The performance qualification is conducted in triplicate with the dosimeters placed throughout the product to assess both the dose distribution and determine the variability of the absorbed dose measurements, when processed under the same processing conditions.

Following processing the relationship between $\overline{D_{ref}} / \overline{D_{min}}$ and $\overline{D_{ref}} / \overline{D_{max}}$ are calculated to determine an acceptable D_{Ref} processing range.

D_{Ref} processing range is calculated by multiplying the R_{min} by the Customer minimum specification and the R_{max} by the Customer maximum specification. During routine processing if the D_{Ref} value falls within this range then processing is deemed as meeting the required specification:

D_{Ref} Minimum = Expected value of R_{min} x Minimum Dose Required
D_{Ref} Maximum = Expected value of R_{max} x Maximum Dose Required

Uncertainty

The specification for D_{Ref} incorporates an estimation of the uncertainty associated with the measurement system. Uncertainty has been calculated using the method outlined in ASTM E 2303-03. This method provides a confidence level of 95%.

Definitions

D_{Ref} - Reference Dose
D_{Min} - Minimum Dose
D_{Max} - Maximum Dose
R_{min} - D_{Ref}/D_{Min} ratio
R_{max} - D_{Ref}/D_{Max} ratio
CV% - Coefficient of Variance
Co60 - Cobalt 60

Product description: KIMTECH Pure* G3 Sterile Sterling Nitrile Gloves - 12" Hand Specific Pairs - Low Density

Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
A11	31.6	31.6	31.3	31.5	**0.17**	**0.54**	
A21	30.6	31.4	31.8	31.3	0.61	1.95	0.75
A31	30.0	31.8	29.5	30.4	1.21	3.98	2.93
A41	30.4	31.1	31.0	30.8	0.38	1.23	0.29
A51	31.1	32.3	32.7	32.0	0.83	2.59	1.39
A15	32.2	32.2	31.9	32.1	0.17	0.53	0.06
A25	32.0	32.2	32.6	32.3	0.31	0.96	0.19
A35	32.4	32.0	31.4	31.9	0.50	1.57	0.51
A45	32.0	32.5	31.3	31.9	0.60	1.88	0.73
A55	32.8	32.4	32.8	32.7	0.23	0.70	0.11
A19	**34.8**	**34.9**	34.4	**34.7**	0.26	0.75	0.14
A29	33.4	32.7	33.7	33.3	0.51	1.53	0.53
A39	34.5	33.0	**34.5**	34.0	0.87	2.56	1.50
A49	33.8	33.7	34.4	34.0	0.38	1.12	0.29
A59	33.5	34.6	34.0	34.0	0.55	1.62	0.61
B11	26.7	26.9	26.3	26.6	0.31	1.17	0.19
B21	26.5	26.2	26.7	26.5	0.25	0.94	0.13
B31	**25.8**	26.0	**25.2**	**25.7**	0.42	1.63	0.35
B41	27.4	**25.9**	26.4	26.6	0.76	2.86	1.17
B51	27.0	27.0	26.9	27.0	0.06	0.22	0.01
B15	27.9	28.8	28.0	28.2	0.49	1.74	0.49
B25	27.8	28.4	27.9	28.0	0.32	1.14	0.21
B35	28.5	28.1	27.5	28.0	0.50	1.79	0.51
B45	28.2	29.2	28.7	28.7	0.50	1.74	0.50
B55	28.0	29.4	28.2	28.5	0.76	2.67	1.15
B19	30.0	31.7	30.5	30.7	0.87	2.83	1.53
B29	30.5	30.8	30.4	30.6	0.21	0.69	0.09
B39	30.7	31.5	30.3	30.8	0.61	1.98	0.75
B49	31.4	30.2	31.2	30.9	0.64	2.07	0.83
B59	30.6	31.4	31.5	31.2	0.49	1.57	0.49

Pooled variance (s2overall) **0.32**
Minimum detectable difference (б) **0.77**
Mean Minimum dose (DMin) **25.7 (B31)**
Mean Maximum dose (DMax) **34.7 (A19)**

Isotron Ratio	
1/Rmin	**0.816**
1Rmax	**1.101**

Expected value of Rmin **1.226**
Expected value of Rmax **0.908**

Customer Spec Min **25.0** Max **50.0**

Dref Minimum **30.7**
Dref Maximum **45.4**

Product description: KIMTECH Pure* G3 Sterile Sterling Nitrile Gloves - 12" Hand Specific Pairs - High Density

Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
A11	31.8	31.3	31.4	31.5	**0.26**	**0.83**	
A21	31.6	29.6	29.4	30.2	1.22	4.04	2.96
A31	30.3	29.7	29.1	29.7	0.60	2.02	0.72
A41	30.9	30.5	30.3	30.6	0.31	1.01	0.19
A51	31.1	32.5	32.1	31.9	0.72	2.26	1.04
A15	31.1	30.9	32.2	31.4	0.70	2.23	0.98
A25	30.2	29.7	30.3	30.1	0.32	1.06	0.21
A35	30.8	28.6	29.3	29.6	1.12	3.78	2.53
A45	31.1	30.1	30.3	30.5	0.53	1.74	0.56
A55	32.5	32.1	32.4	32.3	0.21	0.65	0.09
A19	**34.5**	**34.3**	32.5	**33.8**	1.10	3.25	2.43
A29	32.8	32.7	33.1	32.9	0.21	0.64	0.09
A39	33.4	32.8	33.0	33.1	0.31	0.94	0.19
A49	32.9	32.8	32.4	32.7	0.26	0.80	0.14
A59	33.6	33.2	**34.3**	33.7	0.56	1.66	0.62
B11	26.6	26.5	27.8	27.0	0.72	2.67	1.05
B21	26.1	26.4	26.3	26.3	0.15	0.57	0.05
B31	25.7	**25.4**	**25.6**	**25.6**	0.15	0.59	0.05
B41	**25.2**	25.7	26.3	25.7	0.55	2.14	0.61
B51	26.3	26.0	27.1	26.5	0.57	2.15	0.65
B15	26.9	26.8	27.9	27.2	0.61	2.24	0.74
B25	26.7	26.1	26.2	26.3	0.32	1.22	0.21
B35	26.0	25.5	25.9	25.8	0.26	1.01	0.14
B45	26.7	25.8	27.2	26.6	0.71	2.67	1.01
B55	27.1	27.5	28.1	27.6	0.50	1.81	0.51
B19	30.3	30.9	29.9	30.4	0.50	1.64	0.51
B29	29.0	28.8	29.2	29.0	0.20	0.69	0.08
B39	30.2	29.1	28.5	29.3	0.86	2.94	1.49
B49	30.4	28.5	28.4	29.1	1.13	3.88	2.54
B59	30.1	29.3	29.4	29.6	0.44	1.49	0.38

Pooled variance ($s^2_{overall}$) **0.39**

Minimum detectable difference (б) **0.85**

Mean Minimum dose (D_{Min}) **25.6 (B31)**

Mean Maximum dose (D_{Max}) **33.8 (A19)**

Isotron Ratio	
1/Rmin	**0.812**
1Rmax	**1.073**

Expected value of R_{min} **1.231**

Expected value of R_{max} **0.932**

Customer Spec Min **25.0** Max **50.0**

Dref Minimum **30.8**

Dref Maximum **46.6**

Product Detail

Customer Name: **Safeskin Medical & Scientific (Thai) Ltd**
A/C No: **SAF002** Report Ref.: **0.0358**
Issue Date: **08.03.2011** Expiry Date: **08.03.2016**

Product Description: **KIMTECH Pure* G3 Sterile Sterling Nitrile Gloves- 12" Hand Specific Pairs - Low density**

Product weight : **7.49 kg**
Carton dimension : **345 (L) x 265 (W) x 370 (H)**
Density : **0.221 g/cm3**
Plant Batch No: **M211030093**
Current Cobalt Loading (Mc_i): **3861423**
Standard Plant Dwell Time (sec): **171** Dwell Time (sec): **171**
Number of Xs: **38.08** Value of X: **4.49**
Dose Range Specification (kGy): **25.0** Min. **50.0** Max.

Minimum dwell time to achieve	Minimum dose	Maximum dose
First tote	166	246
Second tote	165	**245**
Third tote	**170**	248

Product Description: **KIMTECH Pure* G3 Sterile Sterling Nitrile Gloves- 12" Hand Specific Pairs - High density**

Product weight : **9.30 kg**
Carton dimension : **345 (L) x 265 (W) x 370 (H)**
Density : **0.275 g/cm3**
Plant Batch No: **M211030094**
Current Cobalt Loading (Mc_i): **3861423**
Standard Plant Dwell Time (sec): **171** Dwell Time (sec): **171**
Number of Xs: **38.08** Value of X: **4.49**
Dose Range Specification (kGy): **25.0** Min. **50.0** Max.

Minimum dwell time to achieve	Minimum dose	Maximum dose
First tote	**170**	**248**
Second tote	168	249
Third tote	167	249

Customer Name: **Safeskin Medical & Scientific (Thai) Ltd.**

Type of Package: **Corugated Carton**

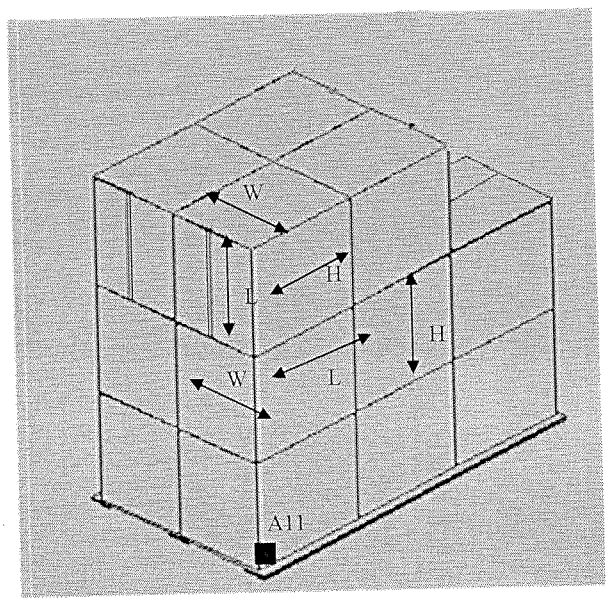
Product Description: **KIMTECH Pure* G3 Sterile Sterling Nitrile Gloves- 12" Hand Specific Pairs**

Issue Date: **08.03.2011**

Fit Per Tub: **16**

Expiry Date: **08.03.2016**

This performance qualification relates only to the above product loaded in the configuration outlined below.



Authorised By:	Signature	Date
QA Manager		11/03/11

Customer Name: **Safeskin Medical & Scientific (Thai) Ltd.**

Type of Package: **Corugated Carton**

Product Description: **KIMTECH Pure* G3 Sterile Sterling Nitrile Gloves- 12" Hand Specific Pairs**

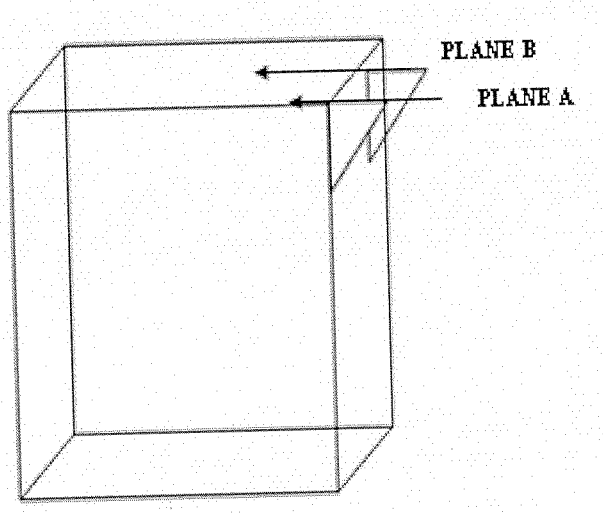
Issue Date: **08.03.2011**

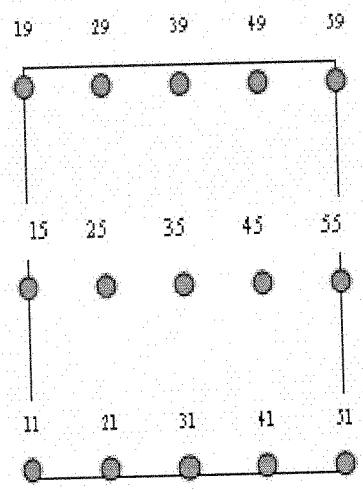
Fit Per Tub: **16**

Expiry Date: **08.03.2016**

This performance qualification relates only to the above product loaded in the configuration outlined below.

LOCATION OF DOSIMETERS





As per our Operational Qualification Report, Source Loading 20th replenished on 22nd Sept 2010, the dose distribution in the front plane (plane A) is the same as in the back plane.

Authorised By:	Signature	Date
QA Manager		11/03/11

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: $= \frac{(AnalyteConc.) * (500ml)}{GloveWeight}$

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

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.

Test Method for Analyzing Bacterial Endotoxins

This test method is used to detect or quantify endotoxins in sterile medical and cleanroom gloves

1. Scope
    1.1 The test method is a kinetic turbidimetric method used to detect or quantify Gram-negative bacteria using Limulus Amoebocyte Lysate (LAL) from horseshoe crab (*Limulus polyphemus or Tachypleus tridentatus*).
    1.2 The average contaminant concentration will be reported in endotoxin units per device (pair)
    1.3 This procedure is an overview of the Kimberly-Clark Internal procedure
    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 U.S. Pharmacopoeia USP 24 NF 19, Second Supplement, Bacterial Endotoxin Test.
    2.2 ASTM D7102-10 Standard Guide for Determination of Endotoxin on Sterile Medical Gloves.

3 Apparatus
    3.1 Microplate reader
    3.2 Computer and windows software
    3.3 Hot air oven capable of 250C
    3.4 Refrigerator capable of 5C
    3.5 Freezer capable of -10 to -20C
    3.6 Vortex mixer
    3.7 Incubator capable of 180 rpm, 35C
    3.8 Timer
    3.9 Micropipettor: single and 8 channel
    3.10 Laminar flow hood
    3.11 96 well flat bottom microplate, sterile, non-pyrogenic, individually wrapped
    3.12 Sterile, non-pyrogenic pipette tips
    3.13 Aluminum foil
    3.14 Glass beaker 600 mL, 1000 mL
    3.15 Glass tube
    3.16 Pyrogent®-5000 test kit catalog N383 or N384 (BioWhittaker, Inc)
    3.17 Pyrogenic-free water

4 Test Preparation:

4.1 All glassware used for assay must be depyrogenated in a hot air oven at temperature 250C for 2 hours

4.2 All surface areas must be cleaned with 70% ethyl alcohol solution

4.3 Glove Sample preparation:

4.3.1 Transfer 10 gloves into a 600 or 1000 mL beaker and add 400 mL of pyrogen-free water (only exterior of the gloves are soaked with water)

4.3.2 Cover beaker with pyrogen-free aluminum foil and place in incubator shaker at 180 rpm, for 60 minutes at 35C

4.3.3 After extraction is completed take the beakers outs, discard the gloves from the solution.

4.3.4 Store the test solution at 2-8C

4.3.5 Perform dilution of test solution as necessary for testing

4.4 Reagent, standard endotoxin stock and CSE preparation:

4.4.1 LAL reagent (lysate):

4.4.1.1 allow reconstitution buffer to warm to room temperature before use

4.4.1.2 Reconstitute lysate with reconstitution buffer as per test kit instruction

4.4.1.3 Swirl gently to avoid foaming

4.4.2 Standard Endotoxin stock solution:

4.4.2.1 Reconstitute endotoxin with specified volume to pyrogen-free water

4.4.2.2 Shake vigorously for 15 min at high speed on a vortex mixer.

4.4.3 Control standard endotoxin (CSE):

4.4.3.1 Prepare the CSE per manufacturer's instruction. Prepare serial dilutions (4) as necessary

4.5 LAL Testing

4.5.1 Carefully dispense 100 uL pyrogenic-free water (blank or negative control), positive control, 4 concentrations of CSE and diluted test solution into microtiter wells of microplate. Bubbles must be avoided

4.5.2 Place filler plate into microtiter reader (ensure temperature is at 37C)

4.5.3 When the assay is finished, print standard curve results and calculate results vs. the standard.

Kimberly-Clark PROFESSIONAL*

Glossary of Terms

Item	Definition
Anion	The ion in an electrolyzed solution that migrates to the anode when voltage is generated; broadly: a negatively charged ion. Typical examples include Chloride (Cl-), Phosphate (PO4-3), Sulfate (SO4-2), Nitrate (NO3-).
AQL	Acceptable Quality Level. Applies to product attributes and defines the allowable number of defects for various sample sizes. For example, AQL 1.5 means that the sample must demonstrate that it exceeds 1.5% defects in order to reject the sample.
ASTM	American Society of Testing and Materials. The ASTM issues testing standards and specifications. The FDA utilizes many of the standards developed by the ASTM to establish medical device requirements.
Average	The sum of individual observations divided by the total number of observations. Average represents the central tendency of a "sample" group. The sample group can be used to make inferences about the entire population.
Bioburden	Bioburden is the population of viable microorganisms on a raw material, component, a finished product and/or a package. When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item.
Biocompatibility	The property of not causing cytological change when introduced to a biological system or model.
Calcium carbonate	A mold-release agent often used that facilitates the release of latex gloves from their porcelain molds (formers). Calcium carbonate is a non water-soluble crystal. It occurs in nature as oyster shells, chalk and limestone.
Calibration	Comparison of a measurement standard or instrument of unknown accuracy with another standard or instrument of known accuracy to detect, correlate, report, or eliminate by adjustment, any variation in the accuracy of the unknown standard or instrument.
Cation	The ion in an electrolyzed solution that migrates to the cathode when voltage is generated; broadly: a positively charged ion. Typical examples include: Sodium (Na+), Calcium (Ca2+), Magnesium (Mg2+), Potassium (K+).
CE Mark	What is CE Marking? CE Marking is the symbol as shown on the top of this page. The letters "CE" are the abbreviation of French phrase "Conformité Européene" which literaturely means "European Conformity".
Certificate of Analysis (CoA) for cleanroom gloves	An authenticated document issued by the manufacturing plant that certifies the quality and purity of the cleanroom glove products being exported.
Certificate of Irradiation (CoI) for cleanroom sterile gloves	An authenticated document issued by the sterilization plant that certifies the sterile cleanroom gloves as having been irradiated. Document includes the manufacturer lot & batch number. Irradiation data, allowable dose range and actual dose.
CFU (colony forming units)	Either one or an aggregate of many microbial cells which, when cultivated on solid media, will develop into a single visual colony. The unit of measure used for reporting bioburden (CFU/product).
Cleanroom	A room in which the concentration of airborne particles is controlled to specified limits. Federal Standard 209E - A document that establishes standard classes of air cleanliness for airborne particulate levels in cleanrooms and clean zones.
Contact sensitizer (other keywords: accelerators, MBT, carbamate, thiurams, mercaptobenzothiazole)	A chemical agent used in the manufacturing process of gloves that may elicit a delayed type allergic reaction (Type IV) after repeatedly exposing the substance to a susceptible individual.
Deionize	To remove ions. Deionization is generally the removal of ions from water by a process called ion exchange. Water is passed over a resin (plastic) exchange bed. The ions in the water have a greater attraction to the exchange bed than to the water.
Do we have sulfur in our gloves?	All latex (both NRL and Nitrile) use native S as a cross link element. Vinyl gloves do not typically have sulfur.
Dose audit	A check to make sure the dose is still correct. The population and sterilization resistance of microorganisms vary with environmental conditions such as temperature and moisture.
Dose mapping	Product dose mapping is conducted to identify the zones of minimum and maximum dose, within the product load with the specified loading pattern, and to assess the reproducibility of the process.
Dose setting	"Dose Setting using Bioburden Information." Determine the number of organisms on the packaged, pre-sterilized gloves.
Dosimeter	A device that measures the amount of radiation which reaches the position where the dosimeter is placed.
Elongation	Measurement in percent of the length a glove material can be stretched before it breaks.
Endotoxin	Pieces off the cell wall of dead bacteria, capable of causing multiple local and systemic pathological problems, including fever, complement activation, cell lysis, tissue inflammation, diarrhea, microthrombi formation (clots) and disseminated intravascula.

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Glossary of Terms

Enzyme-Linked Immunosorbent Assay (ELISA)	A highly sensitive immunoassay for specific antibodies or antigens (including allergens) depending on how the test is set up. Results expressed as mg/g or mL; ppm; Au/g or mL.
Gamma Irradiation	The process of product sterilization utilizing gamma wave radiation. It is the most compatible sterilization process for latex gloves.
Good Manufacturing Practices (GMPs)	What are GMPs? Good Manufacturing Practices (GMPs) are regulations that describe the methods, equipment, facilities, and controls required for producing: human and veterinary products (21 CFR 210-211), medical devices (21 CFR 820), processed food.
IEST	Institute of Environmental Standards and Technology. A consortium that develops standards and recommended practices and provides training by industry experts. The standards and recommended practices are developed by committees comprised of scientists.
Ion	An atom or group of atoms that carries a positive or negative electric charge.
ISO	The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. ISO has developed a series of standards relating to Quality Systems known as the ISO 9000 family standards.
ISO 9002	A quality system model for quality assurance in production and installation. I would skip ISO 9003 because it implies like 9002 doesn't cover inspection and testing.
Latex	Commonly, it is a milky, usually whitish fluid obtained from over 1,000 species of trees and plants. Relating to gloves, it is natural rubber latex, the raw material which comes from the Hevea brasiliensis tree.
Leaching	Process applied in the production of gloves by which chemicals or contaminants are dissolved and carried away by water to reduce chemical residual levels. Wet gel leaching occurs right after latex is dipped onto the mold.
Lowry	Determines the concentration of total protein present in a sample. A Modified Lowry assay was developed for use with latex products.
Mean	Represents the "Central Tendency" or average of an entire population. The formula is the same as for the average, except the mean includes the entire population. It is typically impractical to measure every member of any population.
Method 1	Dose setting utilizing the number (bioburden) and resistance of micro-organisms on the products to determine the level of irradiation necessary for sterilization with the desired safety margin (e.g. 10-6).
Micrometer (micron)	A unit of measurement equal to one-millionth of a meter or approximately 0.00003937 inch (e.g. 25 micrometers are approximately 0.001 inch).
Micron	A unit of length equal to one millionth (10-6) of a meter.
Modified Lowry assay	See Lowry.
Modulus	A measurement of the resistance to stretch. A lower modulus represents a glove in which it is easier to move and thus less fatiguing.
Non-pyrogenic	Non-fever causing. Reflects low levels of endotoxins which cause fever, inflammation, endotoxic shock, elicit micro-thrombi formation and numerous other adverse conditions. (See Endotoxin)
NVR (Non-Volatile Residues)	Refers to materials or components that do not evaporate at normal temperature and pressure.
Particle	A solid or liquid object, generally between .001 micron and 1000 microns in size.
Particle Size	The maximum linear dimension of a particle as observed with an optical microscope or the equivalent diameter of a particle detected by an instrument.
Particle Size Distribution	The relative percentage by weight or number of different particle size fractions.
Particulate	A substance that consists of particles (minute quantities of solid or liquid matter).
pH	Hydrogen ion concentration; measurement of how acidic or basic a glove extract is.
Product Dose Mapping	See "Dose Mapping."
Protein content	Regarding latex gloves, protein content is the measurement of total protein regardless of allergenic content. The ASTM D5712 Modified Lowry assay is the method recognized by the government for use with gloves.
Proteins	Any of a class of naturally occurring complex combinations of amino acids (containing carbon, hydrogen, oxygen, nitrogen, usually sulfur, occasionally phosphorus) which are essential constituents of all living cells.
Pyrogen	A fever-producing substance. Endotoxin is a pyrogen.
Pyrogenic	Capable of eliciting a fever.
SAL	See "Sterility Assurance Level."
SAL Dose	The level of radiation delivered to the product to achieve the required SAL (sterility assurance level).
Sampling	A process consisting of the withdrawal or isolation of the fractional part of a whole. In air or gas analysis, the separation of a portion of an ambient atmosphere with or without the simultaneous isolation of selected components.
Silicone [gloves]	Silicone is a synthetic polymer, or macro-molecule, whose backbone is a repeating chain of Si-O molecules, with various organic groups attached to the silicon. The most common silicone is PDMS, poly-dimethylsiloxane [(CH3)2Si-O).

Glossary of Terms

Silicone-free gloves	Currently, all our cleanroom nonsterile products are silicone free. We do not make the same claim with our boxed products. Some of them have silicone in them.
SPC (Statistical Process Control)	Statistical process control is the practice of using statistical methods such as control charts and capability analysis to monitor and control a process. The application of statistics to determine non-random changes in a process. Any changes or "shifts" in the process will be reflected as non-random occurrences and can be studied for root cause.
Specification – Design	A concise document defining technical requirements in sufficient detail to form the basis for a product or process. It indicates when appropriate, the procedure that determines whether or not the given requirements are satisfied.
Specification – Performance	A concise document that details the performance requirements for a product. The performance specification includes procedures and/or references for testing and certification of the product.
Standard Deviation	A statistical measurement of variability equal to the square root of the arithmetic average of the squares of the deviations from the mean in a frequency distribution.
Static Decay	The materials ability to dissipate a charge. Normally tested by placing a known charge (5000 volts) on the material (glove). A non-contact meter measures the charge on the material.
Static Dissipative	A property of material having a surface resistivity of at least 105 OHMs per square, but less than 1.0 x 1012 OHMs per square surface resistivity.
Statistical Capability	A process with a Cpk > 1.0 (although this can be defined as > 1.33 as well).
Statistical Control	A process which, when sampled on a regular basis, demonstrates an average that is consistent with the population central tendency and variability. In other words, the sample is statistically from the same population as previous samples.
Sterile	Assurance that a given device is without living organisms.
Steriliy Assurance Level (SAL)	The expected probability of an item being non-sterile after exposure to a valid sterilization process. This is a safety factor over and above demonstrating that all microorganisms are killed.
Sterilization	A physical or chemical process that completely destroys or eliminates all forms of microbial life.
Sterilization Dose	Minimum absorbed dose required to achieve the specified sterility assurance level.
Sterilization Label	Label on the outside of every sterile cleanroom glove case showing the certificate number and sterilization batch. The label also provides a sterility indication showing the case has been irradiated/sterilized.
Sterilization Validation	Establishing documented evidence the sterilization process, dose range and dwell time are appropriate for the product being sterilized.
Synthetic rubber	Not of natural origin; produced by chemical synthesis. Synthetic gloves include, but are not limited to, vinyl (PVC), neoprene (chloroprene), nitrile, viton (fluorocarbon rubber), styrene butadiene (SBR), Tactylon (Styrene-Ethylene- Butadiene-Styrene—SE).
Talc	Magnesium silicate, Mg3Si4O10(OH)2, used as a solid lubricant. Banned from use on surgical gloves after found to cause granulomas and adhesions in surgical wounds.
Technical Data Sheet	Data sheet summarizing Kimberly-Clark's glove technical claims for our customers.
Tensile strength	Measurement of the amount of stretch or pull required to rupture or break the glove material. Measurement is in Pa's or MPa's.
Validation	Establishing documented evidence that a system does what it purports to do.
Vulcanization	The process of treating crude latex, subjecting it to heat and sulfur to render it non-sticky, increasing its strength and elasticity.
What is a polymer?	Polymers are primarily made of carbon, hydrogen and oxygen. The structure of polymers is like a chain where repeating units (-mers) are connected many (-poly) times.
What is ESD (Electrostatic Discharge)? [cleanroom gloves]	The rapid, spontaneous transfer of electrostatic charge. Usually the charge flows as a spark between two bodies with differing electrostatic potentials (voltages) as they approach one another. (ESD Assoc.)
What is the melting point of latex and nitrile gloves?	Akron Rubber Development Laboratory has determined that the melting point of nitrile is at 283.4 Celsius.
What is the relationship between non-volatile residue testing and particle counting? (gloves)	NVR is determined by weight, and particles definitely have weight, but not enough to be a measurable part of the NVR for most cleanroom consumables. The weight of particles depends on their volume and what their made of.

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