Kimberly-Clark PROFESSIONAL*

KIMTECH PURE* G3 Sterile Latex Gloves

DATA PACK

KIMTECH PURE* BRAND

Kimberly-Clark PROFESSIONAL*

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KIMTECH* BRAND

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TECHNICAL DATA SHEET

www.kimtech.com
800-255-6401

KIMTECH PURE* G3 Sterile Natural Rubber Latex† Gloves

Formerly SAFESKIN® Sterile Critical Natural Rubber Latex Gloves

Product Information

Code	*Formerly Coded*	Description	Size
56843	*HC1360S*	**KIMTECH PURE* G3 Sterile Latex† Gloves**	6
56844	*HC1365S*	**KIMTECH PURE* G3 Sterile Latex† Gloves**	6.5
56845	*HC1370S*	**KIMTECH PURE* G3 Sterile Latex† Gloves**	7
56846	*HC1375S*	**KIMTECH PURE* G3 Sterile Latex† Gloves**	7.5
56847	*HC1380S*	**KIMTECH PURE* G3 Sterile Latex† Gloves**	8
56848	*HC1385S*	**KIMTECH PURE* G3 Sterile Latex† Gloves**	8.5
56849	*HC1390S*	**KIMTECH PURE* G3 Sterile Latex† Gloves**	9.0
56842	*HC1310S*	**KIMTECH PURE* G3 Sterile Latex† Gloves**	10.0

Material: Natural Rubber Latex. Silicone-free.
Protein: Fifty (50) micrograms or less of total water extractable protein per gram, as measured by ASTM D 5712, "Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method."
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, 20 pairs/ double poly bag, 10 double bags (200 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						
Before Aging	24 MPa, min.		750%, min.						ASTM D 412 and D 573
After Accelerated Aging	18 MPa, min.		560%, min.						
Dimensional	Measured Point	mm	mils						
Nominal Thickness	Middle finger	0.22	8.7						ASTM D 3767 and D 3577
	Palm	0.10	7.9						
	Cuff	0.16	6.3						
Nominal Length	305mm								
Palm Widths	6	6.5	7	7.5	8	8.5	9	10	
Nominal Width (mm)	77	83	89	95	102	108	114	130	ASTM D 3767 and D 6319
Particles (maximum)									
Per $cm^2 \geq 0.5$ micron	1500								IEST-RP-CC005
Endotoxin (maximum)									
Endotoxin Units/pair	20								LAL Kinetic Turbidimetric Method
Total Protein (maximum)									
Micrograms/gram	50								ASTM D 5712

† **Caution:** This Product Contains Natural Rubber Latex, Which May Cause Allergic Reactions. Safe Use Of This Glove By Or On Latex Sensitive Individuals Has Not Been Established.

† **Warning:** This product should not be worn by, or exposed to, individuals allergic to natural rubber latex.

KIMTECH PURE* BRAND

CERTIFICATE OF ANALYSIS

Product Description : **KIMTECH PURE* G3** Sterile Latex Gloves, Hand-Specific Pairs
Catalog Numbers : **HC 1360S, HC 1365S, HC 1370S, HC 1375S, HC 1380S, HC 1385S, HC 1390S, HC 1310S**

Lot # : **420410**
Batches : **SM00912XX to SM01202XX**
Total Cases per Lot : **6217**
Date of Manufacture : **Apr-10**
Expiration Date : **2015 -03**

Physical Test Data**

			Visual Defects		Elongation (%)	Tensile (MPa)
	Watertight	Dimensions	Minor	Major	Pre Aging	Pre Aging
Sample Size :	7690	1660	7780	7780	520	520
AQL Level :	**1.5**	**2.5**	**4.0**	**2.5**	**2.5**	**2.5**
Failures Allowed per AQL :	192	83	447	307	26	26
Failures :	57	0	2	3	0	0
Inspection Results :	**Accept**	**Accept**	**Accept**	**Accept**	**Accept**	**Accept**
				Averages:	**860**	**30.2**

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	219	772	125	508
1.0 - 2.0	17	274	30	60
2.0 - 5.0	5	64	15	19
5.0 - 10.0	0	8	2	3
10.0 - 20.0	0	1	0	0
>20	0	0	0	0
Total per Sample	**272**	**862**	**142**	**590**

Test Method : IEST-RP-CC005.3

Extractable Ion Test Data**

Anions Results

	Fluoride F^-	Chloride Cl^-	Nitrite $N0_2^-$	Bromide Br^-	Nitrate $N0_3^-$	Phosphate $P0_4^{-3}$	Sulfate $S0_4^{-2}$
µg/g glove	**<0.5**	**64.1**	**<2.5**	**<2.5**	**5.2**	**<5**	**3.5**
µg/cm²	<0.003	0.620	<0.016	<0.016	0.050	<0.031	0.034

Cations Results | **Trace Element Results**

	Sodium Na^+	Ammonium NH_4^+	Potassium K^+	Magnesium Mg^{+2}	Calcium Ca^{+2}	Zinc Zn
µg/g glove	**<0.5**	**1.8**	**<0.5**	**<0.25**	**6.1**	**41.1**
µg/cm²	<0.003	0.017	0.003	0.002	0.060	0.402

Test Method : IEST-RP-CC005.3

Endotoxin Data**

Test Result:	**8.338**	**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 : Sonni B.
(QA Executive - SSMT)

CERTIFICATE OF IRRADIATION Number: MA 0027440

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: 4027001595
Date Rec'd: 23/04/10
Date 28/04/10

ITEM CODE ISOTRON BATCH	ITEM SPECIFICATION	QTY	ADDITIONAL DETAILS
M1SAF0050018 M210040202	KIMTECH Pure* G3, Sterile Latex Gloves, Hand Specific 12" Pair Packed 25 kGy-50 kGy	504	

CAT NO	MFG.LOT/BATCH NO	QTY
HC1385S	420310/SM00732XX	1
HC1385S	420410/SM00932XX	20
HC1385S	420410/SM00942XX	9
HC1385S	420410/SM00952XX	36
HC1385S	420410/SM00952XX	36
HC1385S	420410/SM00952XX	7
HC1385S	420410/SM00952XX	36
HC1385S	420410/SM00952XX	11
HC1385S	420410/SM00952XX	24
HC1385S	420410/SM00972XX	32
HC1385S	420410/SM00982XX	4
HC1385S	420410/SM00992XX	27
HC1385S	420410/SM01002XX	9
HC1390S	420410/SM00922XX	4
HC1390S	420410/SM00922XX	4
HC1390S	420410/SM00922XX	28
HC1390S	420410/SM00922XX	2
HC1390S	420410/SM00962XX	8
HC1390S	420410/SM01002XX	26
HC1390S	420410/SM01002XX	22
HC1390S	420410/SM01002XX	7
HC1390S	420410/SM01012XX	36
HC1390S	420410/SM01012XX	36
HC1390S	420410/SM01012XX	19
HC1390S	420410/SM01012XX	17
HC1390S	420410/SM01012XX	36
HC1390S	420410/SM01012XX	7

IRRADIATION DATE:
27/04/2010

ACTUAL DOSE RECEIVED:
MIN:27.7 kGy
MAX:35.9 kGy

Total	504	Last Page 1 of 1

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

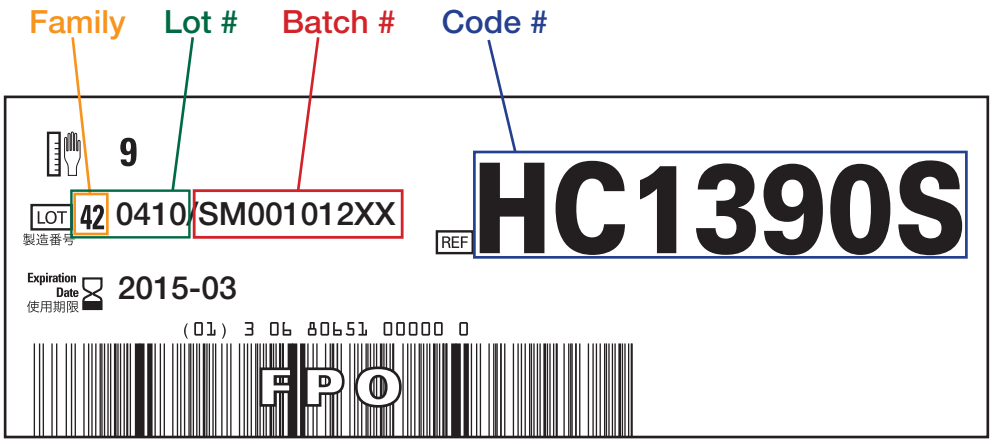
28/04/10

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

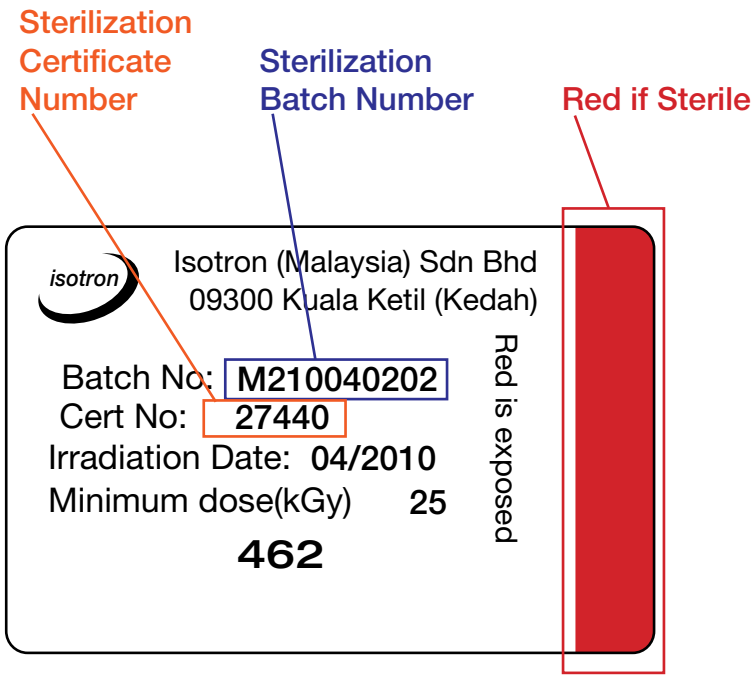
Authorised Signature:

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

Package Label


Family
Lot #
Batch #
Code #
9
LOT
製造番号
42
0410
SM001012XX
REF
HC1390S
Expiration Date
使用期限
2015-03
(01) 3 06 80651 00000 0
FPO

Case Label



Sterilization Label


(EN) Attention: See Insert
(DE) Attention: Voir encart
(ES) Achtung: Siehe Packungsbeilage
(IT) Avviso: Ver hoja insertada
(PT) Atenção: Consultar a literatura inclusa
(JA) インサートをご覧下さい
CE
0123
EN420
Single Use Only
Sterile unless Damaged or Opened.
REF HC1390S
9
LOT 420410/SM01012XX
製造番号
2010-04
2015-03
Date of Manufacture 製造年月
Expiration Date 使用期限
STERILE R
放射線滅菌
AQL 1,5 G1
(01) 1 06 80651 00000 0
Formerly SAFESKIN STERILE CRITICAL
KIMTECH Pure G3 *
1
Sterile Latex Gloves
12" Hand Specific Pairs
(EN) Sterile Natural Rubber Latex Gloves • 12"/30,5 cm Length • For Industrial Use Only • Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions. • Sterile Unless Damaged Or Opened • Single Use Only
(FR) Gants stériles en latex de caoutchouc naturel • Longueur 12"/30,5 cm • Pour usage industriel uniquement • Attention : Ce produit contient du latex de caoutchouc naturel susceptible de provoquer des allergies. • Stériles sauf si l'emballage est endommagé ou ouvert. • Usage unique seulement.
(DE) Sterile Latexhandschuhe (Naturkautschuk) • 12"/30,5 cm Länge • Nur für den industriellen Gebrauch • Achtung: Dieses Produkt enthält Naturkautschuk-Latex und kann allergische Reaktionen hervorrufen. • Steril, solange die Verpackung ungeöffnet und unbeschädigt ist. • Nur zur einmaligen Verwendung.
(BG) Стерилни латексови ръкавици от естествен каучук • 12"/30,5 см дължина • Само за промишлена употреба • Внимание: Този продукт съдържа естествен каучуков латекс, който може да предизвика алергични реакции.
(ES) Guantes estériles de látex de goma natural • 12"/30,5 cm de largo • Sólo para uso industrial • Advertencia: Este producto contiene látex de goma natural, que puede producir reacciones alérgicas. • Estériles siempre y cuando no estén dañados o abiertos. • Úsese una sola vez.
(CS) Sterilní rukavice z přírodního gumového latexu • Délka 12"/30,5 cm • Pouze pro průmyslové použití • Upozornění: Tento výrobek obsahuje přírodní gumový kaučuk, který může vyvolat alergické reakce.
(DA) Sterile handsker af naturgummilatex • 12"/30,5 cm lange • Kun til industribrug • Advarsel: Dette produkt indeholder naturgummilatex, som kan fremkalde allergiske reaktioner.
(ET) Steriilsed naturaalsest kummilateksist kindad • Pikkus 12"/30,5 cm • Ainult tööstuslikuks otstarbeks • Ettevaatust: Toode sisaldab naturaalset kummilateksit, mis võib tekitada allergilist reaktsiooni.
(EL) Αποστειρωμένα γάντια λατέξ από φυσικό καουτσούκ • Μήκος 12"/30,5 cm • Για βιομηχανική χρήση μόνο • Προσοχή: Το παρόν προϊόν περιέχει λατέξ από φυσικό καουτσούκ που μπορεί να προκαλέσει αλλεργικές αντιδράσεις.
(IT) Guanti sterili in lattice di gomma naturale • Lunghezza 12"/30,5 cm • Esclusivamente per uso industriale • Attenzione: prodotto contenente lattice di gomma naturale che può produrre reazioni allergiche.
(LV) Sterili dabiskās gumijas lateksa cimdi • 12"/30,5 cm gari • Tikai industrālai lietošanai • Piesardzība: šis produkts satur dabiskās gumijas lateksu, kas var izraisīt alerģiskas reakcijas.
(LT) Sterilios natūralaus kaučiuko latekso pirštinės • 12"/30,5 cm ilgio • Tik pramoniniam naudojimui • Atsargiai: šio produkto sudėtyje yra natūralaus kaučiuko latekso, kuris gali sukelti alerginę reakciją
(HU) Steril természetes gumi latexkesztyű • 12"/30,5 mm hosszú • Csak ipari használatra • Vigyázat: A termék természetes gumi latexet tartalmaz, amely allergiás reakciót válthat ki.
(NL) Steriele handschoenen van natuurlijk rubberlatex • 12"/30,5 cm lang • Uitsluitend voor industrieel gebruik • Opgelet: Dit product bevat natuurlijk rubberlatex dat allergische reacties kan veroorzaken.
(NO) Sterile hansker av naturgummilateks • 12"/30,5 cm lange • Kun for industribruk • Obs! Dette produktet inneholder naturgummilateks som kan fremkalle allergiske reaksjoner.
(PL) Sterylne rękawice z naturalnej gumy lateksowej • Długość 12"/30,5 cm • Tylko do użytku przemysłowego • Przestroga: Produkt ten zawiera naturalną gumę lateksową, która może wywoływać reakcje alergiczne.
(PT) Luvas esterilizadas de látex de borracha natural • 12"/30,5 cm de comprimento • Somente para uso industrial • Atenção: Este produto contém látex de borracha natural susceptível de provocar reacções alérgicas.
(RO) Mănuşi sterile de latex din cauciuc natural • 12"/30,5 cm lungime • Numai pentru uz industrial • Atenţie: Acest produs conţine latex provenit din cauciuc natural, ceea ce poate cauza reacţii alergice.
(RU) Стерильные перчатки из натурального латекса • Длина 12"/30,5 см • Только для промышленного применения • Осторожно: Этот продукт содержит натуральный каучуковый латекс, который может вызвать аллергические реакции.
(SK) Sterilné rukavice z prírodného gumového latexu • Dĺžka 12"/30,5 cm • Len na priemyselné použitie • Upozornenie: Tento výrobok obsahuje prírodný gumový latex, ktorý môže vyvolať alergické reakcie.
(SL) Sterilne rokavice iz kavčuka iz naravnega lateksa • 12"/30,5 cm dolge • Samo za industrijsko uporabo • Svarilo: Ta izdelek vsebuje kavčuk iz naravnega lateksa, ki lahko povzroči alergične reakcije.
(FI) Steriilejä luonnonkumilateksisia käsineitä • Pituus 12"/30,5 cm • Vain teolliseen käyttöön • Huomautus: Tämä tuote sisältää luonnonlateksikumia, joka voi aiheuttaa allergisia reaktioita.
(SV) Sterila handskar av naturgummilatex • 12"/30,5 cm långa • Endast för industriellt bruk • Var försiktig! Denna produkt innehåller naturgummilatex som kan orsaka allergiska reaktioner.
(TR) Steril Doğal Kauçuk Lateks Eldivenler • 12"/30,5 cm uzunluğunda • Sadece endüstriyel kullanım içindir • Uyarı: Bu ürün alerjik reaksiyona yol açabilen Doğal Kauçuk Lateks içermektedir.
(JA) 滅菌天然ゴムラテックス手袋 • 長さ30.5cm • 産業用途専用 • 注意：この製品は、アレルギー反応を引き起こすこともある天然ゴムラテックスを含んでいます。
LATEX (EN) Contains Latex (FR) Contient du latex (DE) Enthält Latex (ES) Contiene látex (IT) Contém látex (JA) ラテックス含有
EN374-1 (EN) Tested for Watertightness and Low Chemical Protection (FR) Testés pour étanchéité à l'eau et faible protection chimique (DE) Geprüft auf Wasserundurchlässigkeit und geringen Schutz gegen Chemikalien (ES) Sometidos a pruebas de impermeabilidad y protección contra sustancias químicas leves (IT) 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 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 (IT) Comprovadas contra perigos apresentados por microrganismos (JA) 微生物危険性のテスト済み
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www.kcprofessional.com
115054 Россия, Москва, Космодамианская наб. 52/1, 5-й этаж, ООО Кимберли-Кларк
www.kcprofessional.com/ru
06-70-075-0-00
www.kcprofessional.com
Kimberly-Clark Professional

Pouch Label

ISOTRON MALAYSIA SDN BHD

(Company No.: 512058-V)

MS ISO/IEC 17025
TESTING
SAMM NO : 309

ISO 9001 : 2008
CERT NO : FS60510

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.: 803
Purchase Order No.: 4561072439
Isotron sample Log No.: 1234
Isotron Batch No.: M210121009
Date Processed: 08/12/10 & 10/12/10
Product Name: Kimtech Pure* G3 Sterile Latex, Gloves Hand Specific,12" Pairs Packed (HC1300S)
Product Lot No.: SM02932XX
No. of Samples: 100 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

LABORATORY TESTING

SAFESKIN
Medical & Scientific (Thailand) Ltd.

STERILITY TEST REPORT

KIMTECH PURE* G3 STERILE LATEX

GLOVES HAND SPECIFIC ,12" PAIRS PACKED (HC1300S)

TEST REPORT NO. 1012654

NOVEMBER - DECEMBER 2010

Report Prepared By: ..... 20/12/10 ..... Microbiologist

Report Approved By: ..... 20.12.10 ..... 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 6.3 kGy +/- 10 %.

Dose was delivered as follows:

Min 5.9 kGy **Max 6.3 kGy**

100 samples were irradiated and test of sterility was performed on all 100 samples.

STERILITY TESTING

Sample

Kimtech Pure*G3 Sterile Latex Gloves Hand Specific,12"Pairs Packed (HC1300S)
Product Lot No: SM02932XX

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: 803
Test Product: Kimtech Pure*G3 Sterile Latex Gloves Hand Specific,12"Pairs Packed (HC1300S)
Product Lot Number: SM02932XX
Date Samples Received : 22.11.2010
Date Test Carried Out: 15.12.2010
Date Test Complete: 29.12.2010

Signature: .....29/12/10.....

100 samples were tested for sterility.
Growth Promotion : Test media meets the USP 33 <71>

Tryptone Soy Broth (2616TSB02/01/11& 2617TSB 02/01/11)	
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: 2616TSB02/01/11& 2617TSB 02/01/11
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 100 items **TEST PASSED** ☑ **FAILED** ☐
Result: All clear **Signature:** .....29/12/10.....

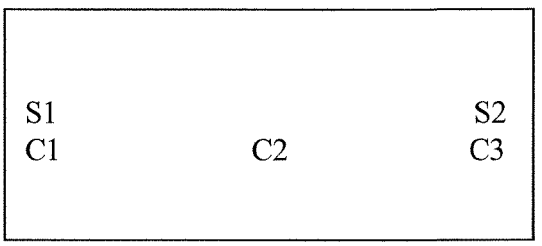
Day	Number Negative	Number Positive	Date	Initials
1	100	Nil	16.12.10	29/12/10
2	100	Nil	17.12.10	29/12/10
3	100	Nil	18.12.10	29/12/10
4	100	Nil	19.12.10	29/12/10
5	100	Nil	20.12.10	29/12/10
6	100	Nil	21.12.10	29/12/10
7	100	Nil	22.12.10	29/12/10
8	100	Nil	23.12.10	29/12/10
9	100	Nil	24.12.10	29/12/10
10	100	Nil	25.12.10	29/12/10
11	100	Nil	26.12.10	29/12/10
12	100	Nil	27.12.10	29/12/10
13	100	Nil	28.12.10	29/12/10
14	100	Nil	29.12.10	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 : 29/12/10

CERTIFICATE OF IRRADIATION

Number: **MA** 0030999 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: M210121009 . DESCRIPTION: KIMTECH PURE*G3 STERILE LATEX GLOVES HAND SPECIFIC,12" PAIRS PACKED (HC1300S) . LOT NO:SM02932XX . IRRADIATION DATE: 08/12/2010 & 10/12/2010 . DOSE REQUIRED: 6.3 kGy +/-10%(5.7 - 6.9 kGy) . ACTUAL DOSE RECEIVED: MIN:5.9 kGy MAX:6.3 kGy
	Total	1	Last Page 1 of 1

STERILITY TEST REPORT 1012654

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

15/12/10

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

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

APPLICATION OF VERIFICATION DOSES

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

Approved by: 16/12/10
Jayanthimala A
QAM

Report number	: 10-245-VD
Sample batch number	: M210121009
Customer name	: Safeskin Medical & Scientific (Thailand) Ltd.
A/C number	: SAF002
Sample description	: Kimtech Pure*G3 Sterile Latex Gloves, Hand Specific, 12" Pairs Packed (HC1300S) Lot no.: SM02932XX

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 6.3 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 5.7 kGy to 6.9 kGy (6.3 kGy ± 10%) and actual dose received were 5.9 kGy to 6.3 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)	:	7.80
Density (g/cm^3)	:	0.23

PROCESSING INFORMATION

Average dose rate	:	1.9 kGy / h
Verification dose requested	:	6.3 kGy ± 10%
Minimum dose less 10% tolerance (rounded off to the upper 0.1 kGy)	:	5.7 kGy
Minimum exposure time (hh:mm)	:	3 hours
Maximum dose plus 10% tolerance (rounded off to the lower 0.1 kGy)	:	6.9 kGy
Maximum exposure time	:	3 hours 38 minutes
Exposure started on / at	:	08 / 12 / 10 at 21:50 and 10 / 12 / 10 at 09:50
Exposure was interrupted for	:	0 minute
Exposure finished on / at	:	08 / 12 / 10 at 22:52 and 10 / 12 / 10 at 12:40
Actual exposure time	:	3 hours 9 minutes

DOSIMETRY RESULTS SUMMARY

	Minimum dose	Maximum dose
Dose requested (kGy)	5.7	6.9
Actual dose received (kGy)	5.9	6.3

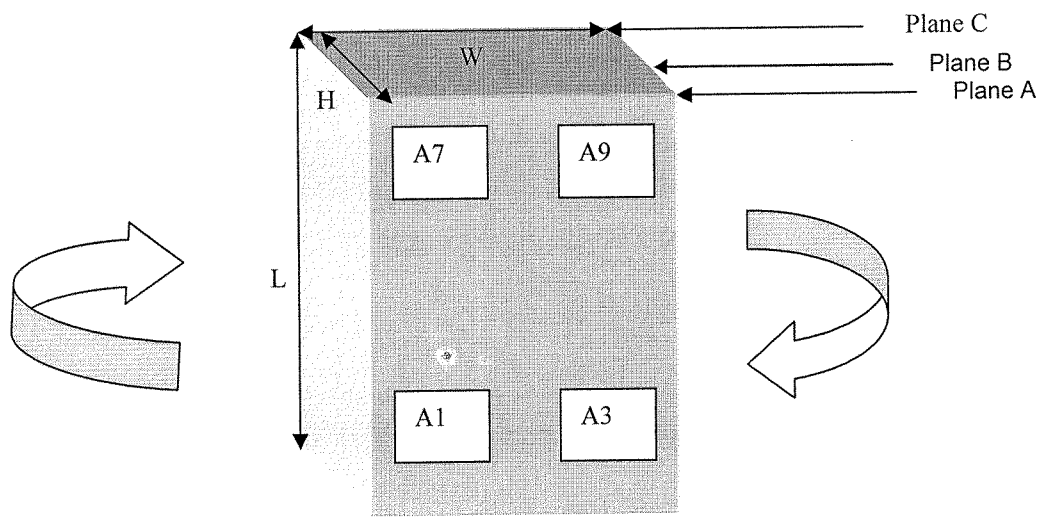
Reference : Attach detailed dosimetry report.

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: M210121009

Number	Optical Density (OD)	Thickness (T)	OD/T	Dose (kGy)	Routine
A1	148	311	0.476	1.8	
A3	146	316	0.462	1.8	
A7	156	298	0.523	2.0	
A9	155	295	0.525	2.0	
B1	141	301	0.468	1.8	
B3	149	314	0.475	1.8	
B7	153	293	0.522	2.0	
B9	155	299	0.518	2.0	

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

Signed: RJB 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: 10/12/10
Customer Name: SAFESKIN
Product description:
Reference: 4561072439
Plant Batch Number and Date: M210121009

Number	Optical Density (OD)	Thickness (T)	OD/T	Dose (kGy)	Routine
A1	295	276	1.069	4.1	
A3	323	298	1.084	4.2	
A7	294	261	1.126	4.3	
A9	326	290	1.124	4.3	
B1	310	293	1.058	4.1	
B3	315	298	1.057	4.1	
B7	362	323	1.121	4.3	
B9	326	291	1.120	4.3	

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

Signed: _____ Dated: 10/12/10

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.

KIMTECH PURE* BRAND

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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