



KIMTECH™

DATA PACK

Kimtech™ G3 sterile Latex Gloves

HC1360S / HC1365S / HC1370S / HC1375S /
HC1380S / HC1385S / HC1390S / HC1310S



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⁽¹⁾For other languages please visit the product page on www.kimtech.eu

⁽²⁾Certificate of Analysis & Certificate of Irradiation are available on a lot by lot basis, please visit www.kimtech.eu/ressources/certificates

EU Declaration of Conformity

Version 1.8 Revision Date: 24.09.2019 DoC #: 100000019626 Date of last issue: 04.02.2019
Date of first issue: 19.07.2018

The manufacturer, and his authorised representative established in the Community, Kimberly-Clark Europe Ltd., confirms that the PPE models, as described, are in conformity with the provisions of Regulation (EU) 2016/425 for category

Style	Product Code(s)	Product Description
Gloves	HC1360S, HC1365S, HC1370S, HC1375S, HC1380S, HC1385S, HC1390S, HC1310S, 56843-25, 56844-25, 56845-25, 56846-25, 56847-25, 56848-25, 56849-25, 56842-25	KIMTECH* G3 Sterile Latex Gloves

Personal Protective Equipment, the European harmonised standard:

Category III PPE

Subject to the procedures set out in Module D of the The Regulation (EU) 2016/425 EC under the supervision of Notified Body.

Harmonized Standards

EN ISO 374-1:2016: (Protective gloves against chemicals and micro-organisms) as a Type C glove against reagent K., EN ISO 374-5:2016: (Protective gloves against chemicals and micro-organisms)with EN 374-2:2014 performance level 2 and including Viral Penetration.


Is identical to the tested samples which are the subject of:

EU type-examination certificate: GB18/961110

Granted to Kimberly - Clark Europe Ltd, based on Technical File by the Notified Body:

PPE.TG.EU.330v00

Signed on behalf of the manufacturer in the European Community.

Liz Brigden		Revision Date: 24.09.2019
Associate Director, Regulatory Affairs		
Kimberly-Clark Europe Ltd.		

As requested by the (EU) 2016/425, addresses of the parts involved as follows:

Kimberly-Clark Europe Limited	SGS United Kingdom Limited (0120)
40 London Road	Unit 202B, Worle Parkway
Reigate, RH2 9QP	Weston-super-Mare, BS22 6WA
Surrey, United Kingdom	United Kingdom
Telephone: +44 1737 736000	Telephone: +44 (0) 1934 522917
Fax: +44 1737 736670	Fax: +44 (0) 1934 522137



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

CERTIFICATE OF ANALYSIS

Product Description : Kimtech* G3 Sterile Latex Gloves, Hand Specific, 12" Pair packed

Catalog Numbers : HC 1360S, HC 1365S, HC 1370S, HC 1375S, HC 1380S, HC 1385S, HC 1390S, HC 1310S

K-C Code : 56843-25, 56844-25, 56845-25, 56846-25, 56847-25, 56848-25, 56849-25, 56842-25

Lot # : 420819

Batches : SM92132XX to SM92432XX
SM92132VX to SM92432VX

Total Cases per Lot : 6,846

Date of Manufacture : Aug-19

Expiration Date : 2024-07

Physical Test Data**

	Watertight	Visual Defects			Dimensions	Elongation (%)		Tensile (MPa)	
		Critical Visual	Major	Minor		Pre Aging	Pre Aging	Pre Aging	Pre Aging
Sample Size :	7265	7265	7265	7265	1480	580	580	580	580
AQL Level :	1.5	1.5	2.5	4.0	2.5	2.5	2.5	2.5	2.5
Failures Allowed per AQL :	173	173	284	414	74	29	29	29	29
Failures :	15	0	3	0	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept	Accept	Accept
Averages:						860	28.08		

Test Methods : Water tight test ASTM D 5151, EN 455-1, Elongation and Tensile ASTM D 412, ASTM D 3577, EN 455-2, Dimension ASTM D 3577, EN 455-2

Particle Test Data**

Particle Size (µm)	Min	Max	Standard Deviation	Average Particles/cm ²
0.5 - 1.0	383	1329	280	814
1.0 - 2.0	36	287	49	81
2.0 - 5.0	11	61	10	20
5.0 - 10.0	2	6	1	3
10.0 - 20.0	1	2	0	1
>20	0	0	0	0
Total per Sample	441	1460	316	920

Test Method : IEST-RP-CC005.4

Extractable Ion Test Data**

	<u>Anions Results</u>						
	Fluoride F ⁻	Chloride Cl ⁻	Nitrite NO ₂ ⁻	Bromide Br ⁻	Nitrate NO ₃ ⁻	Phosphate PO ₄ ⁻³	Sulfate SO ₄ ⁻²
µg/g glove	0.469	63.935	1.407	1.407	7.390	2.345	7.270
µg/cm ²	0.004	0.540	0.012	0.012	0.063	0.020	0.062
	<u>Cations Results</u>				<u>Trace Element Results</u>		
	Sodium Na ⁺	Ammonium NH ₄ ⁺	Potassium K ⁺	Magnesium Mg ⁺²	Calcium Ca ⁺²	Zinc Zn	
µg/g glove	1.916	1.448	1.321	1.268	7.185	45.88	
µg/cm ²	0.016	0.012	0.011	0.011	0.061	0.39	

Test Method : IEST-RP-CC005.4

Endotoxin Data**

Test Result:	BD	Endotoxin Units/ device
Specification:	≤ 20	Endotoxin Units/ device

Detection Limit is ≤ 0.4 EU/device : BD = Below Detection Limit

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

Sterility Data

This product conforms to standards for sterility ISO11737 with sterility assurance level (SAL) 10⁻⁶. A Certificate of Irradiation is also available to assure that the product has received the specified radiation dosage.

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

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Review By :

GK 03 Sept 2019

(QA Manager - SSMT)



<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 13-Aug-2019

MY03S12316534-1-1

This is to certify that Synergy Sterilisation (M) Sdn. Bhd., a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
 EN ISO 9001 Quality Management System
 EN ISO 13485 Quality System - Medical Devices

Safeskin Medical & Scientific (Thailand) Ltd
 200 MOO 8 KANCHANAVANICH ROAD
 PRIK SADAO
 Amphur Sadad
 SONGKHLA 90120
 THAILAND

Other Process Details:

'Kimtech* G3 Sterile Latex Gloves, Hand Specific,12"
 Pair Packed
 'Catalog Numbers : HC1360S, HC1365S, HC1370S,
 HC1375S, HC1380S, HC1385S,
 HC1390S,HC1310S.
 KC Code : 56843-25, 56844-25, 56845-25,
 56846-25, 56847-25, 56848-25, 56849-25,
 56842-25

Catalog Number(s)	Lot No./Batch No.	Quantity
56844-25 HC1365S	420719/SM92102XX	7
56844-25 HC1365S	420719/SM92062XX	29
56845-25 HC1370S	420719/SM92072XX	72
56845-25 HC1370S	420719/SM92062XX	26
56845-25 HC1370S	420719/SM92052XX	138
56845-25 HC1370S	420719/SM92042XX	52
56845-25 HC1370S	420719/SM92032XX	36
56845-25 HC1370S	420719/SM91952XX	9
56845-25 HC1370S	420719/SM91912XX	27
56845-25 HC1370S	420719/SM91832XX	36
56846-25 HC1375S	420719/SM92062XX	36
56846-25 HC1375S	420719/SM92042XX	36
56847-25 HC1380S	420819/SM92132XX	36
56847-25 HC1380S	420719/SM92122XX	20
56847-25 HC1380S	420719/SM92112XX	16
56848-25 HC1385S	420719/SM92102XX	36

Processing Site: Plot 203, Kuala Ketil Industrial Park, Kuala Ketil, 09300 Phone No: +60(0)44152111

Registered Office: Suite 18.01 18th Floor, MWE Plaza, 8, Lebuh Farquhar, 10200, Penang, MALAYSIA

VAT Number: 000859889664

Page 2 of 3

16/08/2019
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 QA Executive
 Synergy Sterilisation (M) Sdn. Bhd.
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Summary of Validation of Kimtech Pure G3 (formerly Safeskin Critical) Latex gloves performed in 2008.

The validation study was performed according to the guidelines established by ANSI/AAMI/ISO 11137:2006 "American National Standard, Sterilization of Healthcare Products—Requirements for Validation and Routine Control—Radiation Sterilization.". The need to re-establish the dose arose from the fact that the packaging was significantly changed. The maximum dose study performed previously established the maximum dose at 50 kGy. The product was tested to be non-bacteriostatic/fungistatic.

Three batches of above-referenced gloves were assayed for bioburden levels. Method 1 was used. The overall average was **24.67 CFU/device**. No single batch was shown to be more than twice this overall average and therefore this overall average was used to calculate the sub process verification dose.

With reference to table 5 of the ISO11137:2006 (this was the current version at that time), the nearest value listed equal to or greater than the bioburden level is 24.67 CFU. Therefore the sub-process dose required for the sterility assurance level of 10^{-2} is 6.3 kGy.

One hundred units were irradiated at this dose and subsequently individually tested for sterility at **6.3+/-10% kGy**.

After full incubation period, there were no growths found. Therefore statistical verification is accepted. Referring to Table 5, to achieve the desired Sterility Assurance Level of 10^{-6} , the minimum dose required is 19.1 kGy.

Submitted by:

A handwritten signature in black ink that reads "Ruthlyn M. Reyes".

Ruthlyn M. Reyes
KCP Operations

Date: January 19, 2010

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 cm² 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 \pm 10 seconds at a rate of 150 rpm \pm 10 rpm.
- 4.2.7. Using clean tongs, immediately remove the glove from the container. Drain any trapped liquid into the beaker by manipulating the fingers on the glove, with the tongs
- 4.2.8. Dispose of the glove.
- 4.2.9. Repeat the extraction two additional times to complete the set.
- 4.2.10. Prepare a process blank, using all the steps in section 4.2, without placing the glove in the Erlenmeyer flask.

4.3. Measurement

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

4.4. Glove Surface Area

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

4.4.2. Record as A.

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

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

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

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

5. Calculations

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

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

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

6. Reporting

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

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

Test Method for Analyzing Extractables

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

1. Scope

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

2. Referenced Documents

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

3. Apparatus

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

4. Procedure

4.1. Test Preparation

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

4.2. Extraction

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

4.13. Measurement

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

4.14. Glove weight and surface area

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

4.14.2. Record as A.

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

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

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

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

5. Calculations

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

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

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



6. Reporting

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

Case Label

G3 Sterile Latex Gloves

7.0

 20 x  10 = 200
12" (30.5cm)

- EN G3 Sterile Latex Gloves
- FR G3 Gants en latex stériles
- ES Guantes estériles de látex G3
- DE G3 Sterile Latexhandschuhe
- NL G3 steriele latex handschoenen
- IT G3 Guanti sterili in lattice
- RU G3 Стерильные латексные перчатки
- UA Рукавички стерильні латексні G3
- PT Luvas de látex estéreis G3
- KO G3 멸균 라텍스 장갑
- JA G3滅菌ラテックス手袋

(EU) **HC1370S**

EN ISO 374-1:2016/Type C

K - Low Chemical

EN ISO 374-5:2016

VIRUS



(US)


56845 **25**

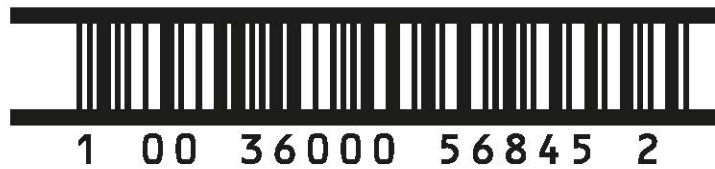
LOT XXXXXX-XXXXXXXXXX
Lot Number
Номер партии
製造番号

 MM-YYYY
Date of Manufacturing
Дата производства
製造年月

 YYYY-MM
Expiration Date
Использовать до
使用期限

CE 0123 EAC
TP-TC 019/2011

 AQL 1.5 Level 2 GI
LM5684525OL-00



Sterile Pair Pouch

Coding Area

LATEX

KIMTECH™

G3 Sterile Latex Gloves

1 **12" (30,5 cm)**

① G3 Sterile Latex Gloves

- 12" / 30,5 cm Length
- Hand Specific Pairs
- Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.**

② G3 Gants en latex stériles

- Longueur 12" / 30,5 cm
- Paires avec main droite et main gauche distinctes
- Attention : Ce produit contient du latex de caoutchouc naturel susceptible de provoquer des allergies.**

③ Guantes estériles de látex G3

- 12" / 30,5 cm de largo
- Específicos para cada mano del par
- Advertencia: Este producto contiene látex de goma natural, que puede producir reacciones alérgicas.**

④ G3 Sterile Latexhandschuhe

- 12" / 30,5 cm Länge
- Handspezifische Paare
- Achtung: Dieses Produkt enthält Naturkautschuk-Latex und kann allergische Reaktionen hervorzufen.**

⑤ G3 stieriele latex handschoenen

- 12" / 30,5 cm lang
- Handspecifieke paren
- Opgelet: Dit product bevat natuurlijk rubberlatex dat allergische reacties kan veroorzaken.**

⑥ G3 Guanti sterili in lattice

- Lunghezza 12" / 30,5 cm
- In paio non ambidestro
- Attenzione: prodotto contenente lattice di gomma naturale che può produrre reazioni allergiche.**

⑦ G3 Стерильные латексные перчатки

- Длина 12" / 30,5 см
- Пары, различие на правую и левую руки
- Осторожно: Этот продукт содержит натуральный латексный материал, который может вызвать аллергические реакции**

⑧ Рукавички стерильні латексні G3

- Довжина 12" / 30,5 см
- Пары, різниця на праву та ліву руки
- ОБЕРЕЖНО: Цей продукт містить гумовий латекс, що може спричинити алергічні реакції.**

⑨ G3 醫用 라텍스 장갑

- 길이 12인치 / 30,5cm
- 손 전용 장갑
- 주의: 이 제품에는 알레르기 반응을 일으킬 수 있는 천연 고무 라텍스가 포함되어 있습니다.**

⑩ G3 滅菌ラテックス手袋

- 長さ 30,5 cm
- 左右別
- 注意: 本品に含まれる天然ゴムラテックスにより、アレルギー反応が起こる可能性があります。**

CE 0123 EAC TPTC 019/2011

STERILE R **AQL 1.5 Level 2 GI**

EN ISO 374-1:2010/Type C **K - Low Chemical**

EN ISO 374-5:2016 **VIRUS**

- ① Protect from Heat and Radioactive Sources
- ② A protéger contre les sources de chaleur et radioactives
- ③ Proteger contra fuentes de calor y radiactividad
- ④ Vor Hitze und radioaktiven Strahlen schützen
- ⑤ 熱源へいりよび放射線を防ぐ
- ⑥ Беречь от нагрева и источников радиоактивного излучения
- ⑦ Оберегати від нагрівання і джерел радіоактивного випромінювання

- ① Keep Dry
- ② Conserver au sec
- ③ Mantener secos
- ④ Trocken halten
- ⑤ 湿気厳禁
- ⑥ Зберігати в сухому місці
- ⑦ Оберегати від вологості

- ① Single Use Only
- ② Usage unique seulement
- ③ Usare una sola vez
- ④ Nur zur einmaligen Verwendung
- ⑤ 再使用禁止
- ⑥ Только для однократного применения
- ⑦ Виключно для однократного застосування

- ① Sterile unless Damaged or Opened
- ② Stériles sauf en cas d'endommagement ou d'ouverture
- ③ Estériles siempre y cuando no estén dañados o abiertos
- ④ Steril, solange die Verpackung ungeöffnet und unbeschädigt ist
- ⑤ 内容物は滅菌済み。包装が開封または破損していません。
- ⑥ Стерильно до момента открытия или повреждения

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