



KIMTECH™

DATA PACK

Kimtech™ G3 sterile White Nitrile Gloves

HC61160 / HC61165 / HC61170 / HC61175 /
HC61180 / HC61185 / HC61190 / HC61110



Table of Content

- › Declaration of Conformity⁽¹⁾
- › Certificate of Analysis⁽²⁾
- › Certificate of Irradiation⁽²⁾
- › Sterile Dose Setting Study
- › Test Method for Analysing Particle Counts
- › Test Method for Analysing Extractables
- › Packaging Components
- › Insert Extract

⁽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

EC Declaration of Conformity

Version 1.0 Revision Date: 31.01.2019 DoC #: 100000005188 Date of last issue: -
 Date of first issue: 31.01.2019

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	HC61160/56888, HC61165/56889, HC61170/56890, HC61175/56891, HC61180/56892, HC61185/56893, HC61190/56894, HC61110/56887	Kimtech Pure G3 Sterile Nitrile Gloves 12" Hand Specific Pairs

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:

EC Certificate of Conformity: GB18/961249

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

PPE.TG.GBL.130.v.00

Signed on behalf of the manufacturer in the European Community.

Liz Brigden		Revision Date: 31.01.2019
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
40 London Road	Unit 202B, Worley 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 White Nitrile Gloves 12" Hand-Specific Pairs

Catalog Numbers : HC61160, HC61165, HC61170, HC61175, HC61180, HC61185, HC61190, HC61110

K-C Code : 56888-26, 56889-26, 56890-26, 56891-26, 56892-26, 56893-26, 56894-26, 56887-26

Lot # : 440819

Batches : SM92132XX to SM92432XX

SM92132VX to SM92432VX

Total Cases per Lot : 3,956

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
						Averages:	578
Sample Size :	4030	4030	4030	4030	960	260	260
AQL Level :	1.5	1.5	2.5	4.0	2.5	2.5	2.5
Failures Allowed per AQL :	95	95	158	227	48	13	13
Failures :	9	0	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept

Test Methods : Water tight test ASTM D 5151, EN 455-1, Elongation and Tensile ASTM D 412, ASTM D 6319, EN 455-2, Dimension ASTM D 6319, EN 455-2

Particle Test Data**

Particle Size (µm)	Min	Max	Standard Deviation	Average Particles/cm ²
0.5 - 1.0	537	663	33	622
1.0 - 2.0	55	164	33	94
2.0 - 5.0	21	47	8	32
5.0 - 10.0	2	13	3	5
10.0 - 20.0	1	5	1	1
>20	0	0	0	0
Total per Sample	739	781	12	755

Test Method : IEST-RP-CC005.4

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	0.588	31.205	1.765	1.765	6.174	2.941	3.568
µg/cm ²	0.004	0.204	0.011	0.011	0.040	0.019	0.023
	Cations Results				Trace Element Results		
	Sodium Na ⁺	Ammonium NH ₄ ⁺	Potassium K ⁺	Magnesium Mg ⁺²	Calcium Ca ⁺²	Zinc Zn	
µg/g glove	3.610	1.376	2.228	1.176	21.823	2.60	
µg/cm ²	0.024	0.009	0.014	0.008	0.143	0.02	

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 :

QK 12 Sept 2019
 (QA Manager - SSMT)



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

Certificate of Irradiation

Date Issued: 05-Sep-2019

MY03S12326449-1-1

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

Order Information

Account Number:	101195
Synergy Health Sales Part Reference:	1126471
Customer Reference Number:	4027014438
Product Description:	KIMTECH*G3 STERILE NITRILE GLOVES,HAND SPECIFIC,12" PAIR PACKED
Validation Reference:	0.0767 Rev01
Quantity Received:	756
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	50.0
Customer Unit Lot/Batch Number:	SEE BELOW

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 1 of 3

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

Certificate of Irradiation

Date Issued: 05-Sep-2019

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

Other Process Details:

Kimtech* G3 Sterile Nitrile Gloves, Hand Specific, 12"
 Pair Packed
 Catalog Numbers: HC61160, HC61165, HC61170,
 HC61175, HC61180, HC61185, HC61190,
 HC61110
 KC Code: 56888-26, 56889-26, 56890-26, 56891
 -26, 56892-26, 56893-26, 56894-26, 56887-26

Catalog Number(s)	Lot No./Batch No.	Quantity
56889-26 HC61165	440819/SM92362XX	72
56889-26 HC61165	440819/SM92352XX	135
56889-26 HC61165	440819/SM92342XX	32
56889-26 HC61165	440819/SM92332XX	13
56890-26 HC61170	440819/SM92352XX	72
56890-26 HC61170	440819/SM92342XX	62
56890-26 HC61170	440819/SM92332XX	43
56890-26 HC61170	440819/SM92322XX	39
56891-26 HC61175	440819/SM92352XX	120
56891-26 HC61175	440819/SM92342XX	46
56891-26 HC61175	440819/SM92332XX	14
56892-26 HC61180	440819/SM92362XX	41
56892-26 HC61180	440819/SM92352XX	20
56892-26 HC61180	440819/SM92342XX	13
56892-26 HC61180	440819/SM92332XX	34

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

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Page 2 of 3

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Certificate of Irradiation

Date Issued: 05-Sep-2019

MY03S12326449-1-1

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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

Irradiation Data

Date and Time of Irradiation:	04-Sep-2019 21:40
Reference Dose Range kGy:	31.4 - 33.2
Calculated Minimum Dose kGy:	27.3
Calculated Maximum Dose kGy:	37.3

Irradiation Release Authorised By Synergy Health Sterilisation UK, a STERIS Company

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, Lebuhr Farquhar, 10200, Penang, MALAYSIA

VAT Number: 000859889664

Page 3 of 3

2019
 05/09/2019
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Summary of current validation of Kimtech Pure G3 White Nitrile gloves code numbers: HC61160, HC61165, HC61170, HC61175, HC61180, HC61185, HC61190, HC61110

The 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 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 **22.33 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 standard, the nearest value listed equal to or greater than the bioburden level is 24 CFU. Therefore the sub-process dose required for the sterility assurance level of 10^{-2} is 6.2 kGy.

One hundred units were irradiated at this dose and subsequently individually tested for sterility at **6.2+/-10% kGy**.

After full incubation period, there were no growths found. Therefore statistical verification is accepted. Referring to Table B.1, to achieve the desired Sterility Assurance Level of 10^{-6} , the minimum dose required is 19.0 kGy.

Submitted by:

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

Ruthlyn M. Reyes
KCP Operations

Date: December 15, 2009

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, 3/4" orbit, capable of 200 rpm
- 3.10. Circular Die, 1.5 inch diameter, calibrated

4. Procedure

4.1. Test Preparation

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

4.2. Extraction

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

4.3. Measurement

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

4.4. Glove Surface Area

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

4.4.2. Record as A.

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

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

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

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

5. Calculations

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

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

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

6. Reporting

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

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

Test Method for Analyzing Extractables

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

1. Scope

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

2. Referenced Documents

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

3. Apparatus

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

4. Procedure

4.1. Test Preparation

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

4.2. Extraction

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

4.13. Measurement

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

4.14. Glove weight and surface area

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

4.14.2. Record as A.

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

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

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

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

5. Calculations

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

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

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



6. Reporting

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

Case Label

G3 Sterile White Nitrile Gloves

7.5

 20 x  10 = 200
12" (30.5cm)

- Ⓜ G3 Sterile White Nitrile Gloves
- Ⓜ G3 Gants stériles blanc en nitrile
- Ⓜ Guantes estériles de nitrilo blancos G3
- Ⓜ G3 Sterile weiÙe Nitrilhandschuhe
- Ⓜ G3 steriele witte nitril handschoenen
- Ⓜ G3 Guanti sterili in nitrile bianchi
- Ⓜ G3 Стерильные белые нитриловые перчатки
- Ⓜ Рукавички стерильні нітрилові білого кольору G3
- Ⓜ Luvas de nitrilo blancas estereis G3
- Ⓜ G3 멸균 화이트 니트릴 장갑
- Ⓜ G3滅菌ホワイトニトリル手袋

(EU) **HC61175**

EN ISO 374-1:2016/type C



K - Low Chemical

EN ISO 374-5:2016



VIRUS



(US)

56891 **26**

LOT

XXXXXX-XXXXXXXXXX

Lot Number
Номер партии
製造番号



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



1 00 36000 56891 9

AQL 1.5 Level 2 GI
LM5689126OL-00

Sterile Pair Pouch



KIMTECH™

G3 Sterile White Nitrile Gloves



Seal Area

Seal Area

- ① G3 Sterile White Nitrile Gloves
 - 12/30,5cm Length
 - Hand Specific Pairs
- ② G3 Gants stériles blancs en nitrile
 - Longueur 12/30,5 cm
 - Paires avec main droite et main gauche distinctes
- ③ Gants estériles de nitrile blancs G3
 - 12/30,5 cm de largo
 - Especificos para cada mano del par
- ④ G3 Sterile weiße Nitrilhandschuhe
 - 12/30,5 cm Länge
 - Handspezifische Paare
- ⑤ G3 steroile witte nitril handschoenen
 - 12/30,5 cm lang
 - Handspecifieke paren
- ⑥ G3 Gants stérils in nitrile blancs
 - Longueur 12/30,5 cm
 - In pairs non ambidextres
- ⑦ G3 Стерильные белые нитриловые перчатки
 - Длина 12/30,5 см
 - Пары, различные на правую и левую руки
- ⑧ Рукавицистерилні білі нитрилові перчатки G3
 - Довжина 12/30,5 см
 - Пары, різні на праву та ліву руки
- ⑨ G3 無菌 화이트 니트릴 장갑
 - 길이 12/30.5cm
 - 손 전용 장갑
- ⑩ G3 無菌 ホワイトニトリル手袋
 - 長さ 30.5 cm
 - 左右別

CE 0123 EN ISO 374-1:2016 Type C EN ISO 374-5:2016

STERILE R

AQL 1.5 Level 2 GI



- ① Protect from Heat and Radioactive Sources
- ② Protéger contre les sources de chaleur et radioactives
- ③ Vor Hitze und radioaktiven Strahlen schützen
- ④ 熱源・放射線から保護
- ⑤ Беречь от нагрева и источников радиоактивного излучения
- ⑥ Оберегти від нагрівання і джерел радіоактивного випромінювання



- ⑦ Keep Dry
- ⑧ Conserver au sec
- ⑨ Mantere secco
- ⑩ Trocken halten
- ⑪ 保持乾燥
- ⑫ Хранить в сухом месте
- ⑬ Зберігти в сухому місці



- ⑭ Single Use Only
- ⑮ Unique utilisation
- ⑯ Usare una sola vez
- ⑰ Nur einmaligen Verwendung
- ⑱ 仅供用一次
- ⑲ Только для однократного применения
- ⑳ Виключно для одноразового використання



- ⑳ Sterile unless Damaged or Opened
- ㉑ Stériles sauf en cas d'endommagement ou d'ouverture
- ㉒ Steriles siempre y cuando no estén dañados o abiertos
- ㉓ Steril, solange die Verpackung ungeschädigt und
- ㉔ 除非损坏或开封，否则保持无菌
- ㉕ Стерильно до момента открытия или повреждения
- ㉖ Стерильно до моменту відкриття або пошкодження

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