

KIMTECH™

Kimtech™ G3 Sterile Sterling™ Nitrile Gloves

11821 / 11822 / 11823 / 11824 / 11825
11826 / 11827 / 11828



DATA PACK



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

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

EU Declaration of Conformity

Version	Revision Date:	DoC #:	Date of last issue: -
1.0	07.10.2022	100000019624	Date of first issue: 07.10.2022

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	11821, 11822, 11823, 11824, 11825, 11826, 11827, 11828	KIMTECH* G3 Sterile STERLING* Nitrile 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 21420:2020 (Protective gloves – General requirements and test methods)

: EN ISO 374-1:2016+A1:2018 (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 374-2:2019 performance level 2 and including Viral Penetration

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

EU type-examination certificate: 0598/PPE/22/3711

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

Body:PPE.TG.GBL.283.v05

Signed on behalf of the manufacturer in the European Community.

Christelle Bouvier		Revision Date: 07.10.2022
Senior Regulatory Affairs Manager		
Kimberly-Clark Europe Ltd.		

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

Kimberly-Clark Europe Limited	
Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, United Kingdom	
Telephone: +44 1737 736000	Fax: +44 1737 736670
SGS FIMKO OY (0598)	
Takomotie 8, HELSINKI, 00380, Finland	
Telephone: +358 9 696 361	Fax:
TÜV SÜD Product Service GmbH Zertifizierstellen (0123)	

EU Declaration of Conformity

Version	Revision Date:	DoC #:	Date of last issue: -
1.0	07.10.2022	100000019624	Date of first issue: 07.10.2022

Ridlerstraße 65, MÜNCHEN, 80339, Germany,	
Telephone: +49 (89) 50084261	Fax:

UK Declaration of Conformity

Version	Revision Date:	DoC #:	Date of last issue: -
1.0	10.10.2022	100000044048	Date of first issue: 10.10.2022

The manufacturer, and his authorised representative established in the United Kingdom, Kimberly-Clark Europe Ltd., confirms that the PPE models, as described, are in conformity with the provisions of Regulation (EU) 2016/425 as brought into UK law and amended.

Style	Product Code(s)	Product Description
Gloves	11821, 11822, 11823, 11824, 11825, 11826, 11827, 11828	KIMTECH* G3 Sterile STERLING* Nitrile Gloves

Personal Protective Equipment:

Category III PPE

Subject to the procedures set out in Module D of the Regulation (EU) 2016/425 as brought into UK law and amended under the supervision of Approved Body

UK Designated Standards:

: EN ISO 21420:2020 (Protective gloves – General requirements and test methods)

: EN ISO 374-1:2016+A1:2018 (Protective gloves against chemicals and micro-organisms) as a Type C glove against reagent K

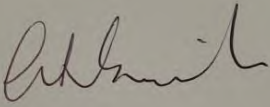
EN ISO 374-5:2016: (Protective gloves against chemicals and micro-organisms) with EN 374-2:2019 performance level 2 and including Viral Penetration

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

UK type-examination certificate:0120/PPE/221011

Granted to Kimberly - Clark Europe Ltd, based on Technical File examination by the Approved Body:PPE.TG.GBL.283.v05

Signed on behalf of the manufacturer in the United Kingdom.

Liz Brigden		Revision Date: 10.10.2022
KCP EMEA Regulatory Affairs Associate Director		
Kimberly-Clark Europe Ltd.		

As requested by the (EU) 2016/425 as brought into UK law and amended, addresses of the parts involved as follows:

Kimberly-Clark Europe Limited	
Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, United Kingdom	
Telephone: +44 1737 736000	Fax: +44 1737 736670
SGS United Kingdom Limited (0120)	
Rossmore Business Park, Ellesmere Port, South Wirral, CH65 3EN, United Kingdom	
Telephone: +44 (0) 1934 522917	Fax:

UK Declaration of Conformity

Version	Revision Date:	DoC #:	Date of last issue: -
1.0	10.10.2022	100000044048	Date of first issue: 10.10.2022

TUV SUD BAPT UNLIMITED (0168)	
Octagon House, Concorde Way, Segensworth North, Fareham, PO15 5RL, Hampshire, United Kingdom	
Telephone: +44 1489 558100	Fax:



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

CERTIFICATE OF ANALYSIS

Product Description : Kimtech* G3, Sterile Sterling Nitrile Gloves, Hand Specific

K-C Code : 11821-40, 11822-40, 11823-40, 11824-40, 11825-40, 11826-40, 11827-40, 11828-40

Lot # : 970123
Batches : SM30012XX to SM30312XX
SM30012VX to SM30312VX

Total Cases per Lot : 553
Date of Manufacture : Jan-23
Expiration Date : 2027-12

Physical Test Data**							
	Watertight	Visual Defects			Dimensions	Elongation (%)	Tensile (MPa)
		Critical Visual	Major	Minor		Pre Aging	Pre Aging
Sample Size :	705	705	705	705	280	120	120
AQL Level :	1.5	1.5	2.5	4.0	2.5	2.5	2.5
Failures Allowed per AQL :	17	17	28	40	14	6	6
Failures :	2	0	0	0	0	0	0
Inspection Results :	Accept	Accept	Accept	Accept	Accept	Accept	Accept
Averages:						584	36.13

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	433	1017	188	702
1.0 - 2.0	30	106	28	72
2.0 - 5.0	11	54	15	28
5.0 - 10.0	1	3	1	2
10.0 - 20.0	1	2	1	1
>20	0	0	0	0
Total per Sample	477	1110	204	806

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	0.858	22.974	2.574	2.574	9.474	4.290	2.265
µg/cm ²	0.004	0.101	0.011	0.011	0.041	0.019	0.010
	Cations Results				Trace Element Results		
	Sodium Na ⁺	Ammonium NH ₄ ⁺	Potassium K ⁺	Magnesium Mg ⁺²	Calcium Ca ⁺²	Zinc Zn	
µg/g glove	2.800	1.716	2.419	1.716	28.108	2.88	
µg/cm ²	0.012	0.007	0.011	0.007	0.123	0.01	

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 ISO11137 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 :

(QA Sr. Manager)

FORM-21963/5

14 Feb 2023


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

Certificate of Irradiation

Date Issued: 27-Jan-2023

MY03S12722659-1-1

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 SADA O
 Amphur Sadad
 SONGKHLA 90120
 THAILAND

Order Information

Account Number:	101195												
Synergy Health Sales Part Reference:	1126466												
Customer Reference Number:	4027021163												
Product Description:	KIMTECH*G3,STERILE STERLING NITRILE GLOVES,HAND SPECIFIC												
Validation Reference:	0.0697 Rev02												
Quantity Received:	93												
Customer Minimum Specification kGy:	25.0												
Customer Maximum Specification kGy:	50.0												
Customer Unit Lot/Batch Number:	SEE BELOW												
Other Process Details:	Kimtech* G3, Sterile Sterling Nitrile Gloves, Hand Specific KC Code: 11821-40, 11822-40, 11823-40, 11824-40, 11825-40, 11826-40, 11827- 40,11828-40												
	<table><tr><th>Catalog Number(s)</th><th>Lot No./Batch No.</th><th>Quantity</th></tr><tr><td>11822-40</td><td>970123/SM30182XX</td><td>21</td></tr><tr><td>11824-40</td><td>971222/SM23632XX</td><td>24</td></tr><tr><td>11825-40</td><td>971222/SM23632XX</td><td>48</td></tr></table>	Catalog Number(s)	Lot No./Batch No.	Quantity	11822-40	970123/SM30182XX	21	11824-40	971222/SM23632XX	24	11825-40	971222/SM23632XX	48
Catalog Number(s)	Lot No./Batch No.	Quantity											
11822-40	970123/SM30182XX	21											
11824-40	971222/SM23632XX	24											
11825-40	971222/SM23632XX	48											

Irradiation Data

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

Registered Office: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang, MALAYSIA

VAT Number: 000859889664

Page 1 of 2

30/01/2023
 NOR AZWIN BT. YUSUF
 QA Executive
 Synergy Sterilisation (M) Sdn. Bhd
 +60(0)44152111



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

Certificate of Irradiation

Date Issued: 27-Jan-2023

MY03S12722659-1-1

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 SADA O
Amphur Sadad
SONGKHLA 90120
THAILAND

Date and Time of Irradiation:	26-Jan-2023 19:27
Reference Dose Range kGy:	30.7 - 31.2
Calculated Minimum Dose kGy:	25.1
Calculated Maximum Dose kGy:	34.4

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: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang, MALAYSIA

VAT Number: 000859889664

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30/01/2023
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SAFESKIN MEDICAL & SCIENTIFIC (TH) LTD

DOSE SETTING VD Max STUDY TO ISO 11137-PART 2:2006

**“STERILIZATION OF HEALTHCARE PRODUCTS RADIATION
ESTABLISHING THE STERILIZATION PART 2:2006”**

**KIMTECH PURE * G3/G5 STERILE STERLING
NITRILE GLOVES**

REPORT NO. 0907371

JUNE - JULY 2009

Report Prepared By: Shafiqah 21/6/09 Microbiologist

Report Reviewed By: [Signature] 21/07/09 QA Manager



SUMMARY

This study was undertaken in accordance with Method VD max²⁵ of “Sterilization of healthcare products – Radiation Part 2 – Establishing the sterilization dose 11137-2:2006. The study was to substantiate a Sterilization dose of 25kGy. 3 batches of Kimtech Pure * G3/G5 Sterling Sterile Nitrile Gloves were assayed for bioburden levels. The overall average for the batch tested was 13.43 /unit sample. No single batch was shown to be more than twice this overall average and therefore this overall average was used to calculate the sub process verification dose.

With reference to Table 9 of the ISO 11137 – 2:2006 document, the nearest value listed equal to or greater than the bioburden level is 14 CFU. Therefore the sub- process dose required for the sterility assurance level of 10^{-1} is 7.5kGy +/- 10% (6.8 kGy – 8.2 kGy).

Therefore 10 units were irradiated at this dose and subsequently individually tested for sterility. After the full incubation period all tests gave a negative result, therefore statistical verification for the sub process dose is accepted.

In conclusion ,a dose of 25kGy will provide a sterility assurance level of 10^{-6} .

Complete Dose Setting Study available on demand

Test Method for Analyzing Liquid Particle Counts

This test method is used to analyze the mobile particle contaminants from cleanroom gloves.

1. Scope

- 1.1. The test method covers the average particulate contamination found on gloves designated for cleanroom applicability.
- 1.2. The average contaminant concentration will be reported in particles per cm^2 in two ways:
 - 1.2.1. By size grouping, 0.5 to 1.0 microns, 1.0 to 2.0 microns, 2.0 to 5.0 microns, 5.0 to 10.0 microns, 10.0 to 20.0 microns, greater than 20.0 microns, and a total particle count greater than 0.5 microns.
 - 1.2.2. Statistical analysis of each grouping consisting of Minimum Value, Maximum Value, Standard Deviation, and Average Value, for each group of individual gloves.
- 1.3. The safe and proper use of gloves is beyond the scope of this test method.
- 1.4. This test method does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this Test Method to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

- 2.1. IEST-RP-CC005.3 Recommended Practice for Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments
- 2.2. Work Instruction

3. Apparatus

- 3.1. Analytical Balance, capable of readability and repeatability to 0.1 mg
- 3.2. Particle Measuring Systems CLS-900 Liquid Particle Counting System
- 3.3. 2000 mL glass beaker or 1000mL glass conical flask
- 3.4. Stainless Steel Forceps, 10" length
- 3.5. 250 ml Volumetric Flask
- 3.6. 500 ml Volumetric Flask
- 3.7. High Purity Deionized Water System, capable of producing 18.2 MOhm quality water
- 3.8. Point of Use Filter, 0.2 micron size
- 3.9. Orbital Shaker, $\frac{3}{4}$ " 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 Sterling* Nitrile Gloves

8.5



30 x  10 = 300

- (EN) G3 Sterile Sterling* Nitrile Gloves
- (FR) G3 Sterling* Gants stériles en nitrile
- (ES) Guantes estériles de nitrilo G3 Sterling*
- (DE) G3 Sterile Sterling* Nitrilhandschuhe
- (NL) G3 steriele Sterling* nitril handschoenen
- (IT) G3 Guanti sterili in nitrile Sterling*
- (RU) G3 Стерильные нитриловые перчатки Sterling*
- (UA) Рукавички стерильні нитрилові G3 Sterling*
- (PT) Luvas de nitrilo Sterling* estéreis G3
- (KO) G3 멸균 Sterling* 니트릴 장갑
- (ZH) G3 无菌 Sterling* 丁腈手套
- (JA) G3 滅菌 Sterling* ニトリル手袋

EN ISO 374-1:2016+
A1:2018/Type C



EN ISO 374-5:2016



VIRUS

11826 40

CE 0123 UK 0168 EAC TPFC 0168/01

LOT XXXXXX-XXXXXXXXXXXX

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

Sterling* and the colour Grey are owned by Halyard Health or it's affiliates and used under license



AQL 1.5

LM11826400L-00

1 00 36000 11826 8

Sterile Pair Pouch



KIMTECH

KDF Artwork



G3 Sterile Sterling™ Nitrile Gloves 12" / 30.5cm - Hand Specific Pairs



☞ G3 Sterile Sterling™ Nitrile Gloves

- 12"/30.5cm Length
- Hand Specific Pairs
- Textured
- Not Made With Natural Rubber Latex
- For the Sterile Critical Cleanroom Environment
- For Industrial Use Only

NOTICE: THIS INSERT SHOULD BE FURNISHED OR MADE AVAILABLE TO THE USERS OF THESE GLOVES AS A SAFETY PRECAUTION.

This is a Category III PPE product certified according to Regulation (EU) 2016/425 and to the Regulation (EU) 2016/425 as brought in the UK law and amended. Risk: Gloves offer protection against chemicals (Splash) and micro-organisms.

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals. The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. It can be different if the chemical is used in a mixture. Degradation results indicate the change in puncture resistance after exposure to the challenge chemical. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in the physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen. Before usage, inspect the gloves for any defect or imperfections. Discard any gloves presenting a defect Refer to enclosed donning and doffing instructions. For single use only. Store in a cool dry place. Dispose of according to local regulations. A list of substances known to cause allergies can be supplied on demand.

CONTACT US: If you have any questions about this product, call the manufacturer at (US) 1-800-255-6401 (EU) +44(0) 1737 736000 (AP) +603 7807 8210

☞ G3 Sterling™ Gants stériles en nitrile

- Longueur 12"/30,5cm
- Paires s'adaptant à la main
- Texturés
- Ne contient pas de latex de caoutchouc naturel
- Pour les environnements critiques stériles
- Utilisés à des fins commerciales seulement

AVIS : PAR MESURE DE SÉCURITÉ, CET ENCART DOIT ÊTRE FOURNI AUX UTILISATEURS DE CES GANTS OU ÊTRE À LEUR DISPOSITION. Il s'agit d'un EPI de catégorie III certifié conforme au Règlement (UE) 2016/425 EEC. Risque : Les gants offrent une protection contre les produits chimiques (éclaboussures) et les micro-organismes.

Ces informations ne reflètent pas nécessairement la durée réelle de protection en milieu de travail ni la différence entre les mélanges et les produits chimiques purs. La résistance aux produits chimiques a été évaluée en laboratoire avec des échantillons prélevés dans la paume seulement et ne concerne que le produit chimique testé. Les résultats peuvent être différents si le produit chimique est utilisé dans un mélange. Les résultats relatifs à la dégradation indiquent le changement dans la résistance à la perforation après l'exposition au produit chimique. Il est recommandé de s'assurer que les gants conviennent à l'usage prévu en conditions réelles car celles-ci peuvent différer de celles du test standard en fonction de la température, de l'abrasion et de la dégradation. Lorsqu'ils sont utilisés, les gants peuvent fournir moins de résistance aux produits chimiques dangereux en raison de changements dans les propriétés physiques. Les mouvements, déchirures, frottements et dégradations engendrés lors du contact avec les produits chimiques, etc. peuvent réduire la durée réelle d'utilisation de façon significative. Dans le cas des produits chimiques corrosifs, la dégradation peut être le facteur le plus important à considérer lors du choix de gants résistants aux produits chimiques. La résistance à la pénétration a été évaluée en laboratoire et ne concerne que l'échantillon testé. Inspecter les gants avant l'utilisation pour vérifier qu'ils ne comportent pas de défauts ou d'imperfections. Jeter les gants présentant un défaut Consulter les instructions ci-jointes pour enfiler et retirer les gants. Usage unique seulement. Ranger dans un endroit frais et sec. Mettre au rebut conformément aux règlements municipaux. Une liste des substances connues pour provoquer des allergies peut être fournie sur demande.

NOUS CONTACTER : Pour tout renseignement concernant ce produit, appeler le fabricant au (Etats-Unis) 1-800-255-6401 (Europe) +44(0) 1737 736000 (Asie-Pacifique) +603 7807 8210

☞ G3 Sterile Sterling™ Nitrilhandschuhe

- 12"/30,5 cm Länge
- Handspezifische Paare
- Texturiert
- Ohne Naturkautschuklatex
- Für die sterilkritische Reinraumumgebung
- Nur für die industrielle Verwendung

HINWEIS: DIESE PACKUNGSBEILAGE SOLLTE ANWENDERN ALS SICHERHEITSVORKEHRUNG AUSGEHÄNDIGT ODER ZUR VERFÜGUNG GESTELLT WERDEN. Dies ist ein nach Kategorie III PSA zertifiziertes Produkt gemäß Verordnung (EU) 2016/425 EWG. Risiko: Handschuhe bieten Schutz gegen Chemikalien (Spritzer) und Mikroorganismen.



Diese Informationen spiegeln nicht die tatsächliche Schutzdauer am Arbeitsplatz und die Differenzierung zwischen Mischungen und reinen Chemikalien wider. Die Chemikalienbeständigkeit wurde unter Laborbedingungen durch ausschließlich an der Handfläche entnommene Proben bestimmt und bezieht sich nur auf die geprüfte Chemikalie. Die Beständigkeit kann unterschiedlich sein, wenn die Chemikalie in einer Mischung verwendet wird. Degradationsergebnisse zeigen die Punktionsbeständigkeit nach Exposition gegenüber der Chemikalie an. Es wird empfohlen, die Eignung der Handschuhe für den vorgesehenen Verwendungszweck zu prüfen, da sich die Bedingungen am Arbeitsplatz von den Prüfbedingungen hinsichtlich Temperatur, Abnutzung und Zersetzung unterscheiden können. Schutzhandschuhe können bei der Verwendung aufgrund von Veränderungen der physikalischen Eigenschaften eine geringere Beständigkeit gegen die gefährliche Chemikalie aufweisen. Bewegungen, Verhakung, Reibung, durch den Kontakt mit Chemikalien verursachte Zersetzung usw. können die tatsächliche Verwendungszeit erheblich verringern. Bei korrosiven Chemikalien kann Zersetzung der wichtigste Faktor sein, der bei der Auswahl von chemikalienbeständigen Handschuhen zu berücksichtigen ist. Der Penetrationswiderstand wurde unter Laborbedingungen geprüft und bezieht sich nur auf die geprüfte Probe. Die Handschuhe vor der Verwendung auf Mängel oder Fehler prüfen. Handschuhe mit Mängeln sind zu entsorgen Siehe beigefügte Anweisungen zum Anziehen und Ausziehen. Nicht zur Wiederverwendung. An einem kühlen, trockenen Ort lagern. Gemäß den lokalen Bedingungen entsorgen. Eine Liste der Stoffe, die bekanntermaßen Allergien auslösen, kann auf Anfrage geliefert werden.

SO KONTAKTIEREN SIE UNS: Bei Fragen zu diesem Produkt rufen Sie bitte den Hersteller an unter der Nummer (US) 1-800-255-6401; (EU) +44(0) 1737 736000; (AP) +603 7807 8210

☞ G3 steriele Sterling™ nitril handschoenen

- 30.5cm/12 inch lang
- Handspecifieke paren
- Getextureerd
- Niet gemaakt van natuurlijke rubberlatex
- Voor steriele kritische schone ruimtes
- Alleen voor industrieel gebruik

WAARSCHUWING: DEZE BLSUITER DIENST ALS VEILIGHEIDSMATREGEEL GEGEVEN TE WORDEN AAN OF TER BESCHIKKING GESTELD TE WORDEN VAN DE GEBRUIKERS VAN DEZE HANDSCHOENEN.

Dit is een persoonlijk beschermingsmiddel van categorie III volgens Verordening (EU) 2016/425/EEG. Risico: Handschoenen bieden bescherming tegen chemische stoffen (spatten) en micro-organismen. Deze informatie is geen weerspiegeling van de werkelijke beschermingsduur in de werkomgeving en de differentiatie tussen mengsels en zuivere chemicaliën. De chemische weerstand is onder laboratoriumomstandigheden beoordeeld op grond van monsters genomen van alleen de palm en heeft alleen betrekking op het geteste chemische product. Het kan anders zijn als het chemische product in een mengsel wordt gebruikt. Verslechteringsresultaten geven de verandering in punctiebestendigheid na blootstelling aan de betreffende chemische stof aan. Het wordt aanbevolen te controleren of de handschoenen geschikt zijn voor het beoogde gebruik omdat de omstandigheden in de werkomgeving kunnen verschillen van de typetest afhankelijk van temperatuur, schuring en afbraak. Bij het gebruik kunnen beschermende handschoenen minder weerstand bieden tegen het gevaarlijke chemische product vanwege veranderingen in de fysieke eigenschappen. Bewegingen, blijven haken, wrijven, afbraak veroorzaakt door contact met het chemische product etc. kunnen de werkelijke gebruiksduur aanzienlijk verminderen. Bij corrosieve chemische producten kan afbraak de belangrijkste factor zijn waarmee rekening moet worden gehouden bij de keuze van chemisch bestendige handschoenen. De weerstand tegen indringen is beoordeeld onder laboratoriumomstandigheden en heeft alleen betrekking op het geteste specimen. Controleer de handschoenen vóór gebruik op beschadiging of onvolkomenheden. Gooi handschoenen met een beschadiging weg

Raadpleeg de bijgevoegde instructies voor aan- en uittrekken. Uitsluitend voor eenmalig gebruik. Op een koele, droge plaats bewaren. Afvoeren volgens de plaatselijke voorschriften. Een lijst van stoffen waarvan bekend is dat ze allergieën veroorzaken, is op aanvraag verkrijgbaar.

CONTACT MET ONS OPNEMEN: Als u vragen hebt over dit product, kunt u de fabrikant bereiken op nr.: (Verenigde Staten) +1-800-255-6401 (Europa) +44(0) 1737 736000 (Azië-Pacifc) +603 7807 8210.

☞ G3 Guanti sterili in nitrile Sterling™

- Lunghezza 12"/30,5 cm
- Paia destri e sinistri
- Ruvidi
- Non prodotto con lattice di gomma naturale
- Per camera bianca critica sterile
- Solo per uso industriale

AVVISO - QUESTO INSERTO DEVE ESSERE FORNITO O RESO DISPONIBILE COME MISURA DI SICUREZZA A COLORO CHE UTILIZZANO QUESTI GUANTI. Questo prodotto è certificato come DPI di categoria III secondo il Regolamento (UE) 2016/425 CEE. Rischio: i guanti offrono protezione contro sostanze chimiche (schizzi) e microrganismi.

Queste informazioni non riflettono la durata effettiva della protezione sul luogo di lavoro e la distinzione tra prodotti chimici miscelati e puri. La resistenza chimica è stata misurata in condizioni di laboratorio su campioni presi solo dal palmo della mano e si riferisce solo al prodotto chimico testato. Può essere diverso se il prodotto chimico viene utilizzato in una miscela. I risultati della degradazione indicano il cambiamento nella resistenza alle perforazioni dopo l'esposizione a sostanze chimiche. Si consiglia di controllare che i guanti siano idonei per l'uso previsto poiché le condizioni del luogo di lavoro possono differire dal tipo di test a seconda della temperatura, abrasione e degradazione. Quando utilizzati, i guanti di protezione possono fornire meno resistenza ai prodotti chimici pericolosi a causa di cambiamenti delle proprietà fisiche. Il tempo effettivo di utilizzo può essere ridotto significativamente a causa di movimenti, sfilacciamento, strofinamento o degradazione dovuti al contatto con prodotti chimici, ecc. In caso di contatto con prodotti chimici corrosivi, il fattore più determinante da considerare nella scelta di guanti resistenti ai prodotti chimici è la resistenza alla degradazione. La resistenza alla penetrazione è stata misurata in condizioni di laboratorio e riguarda solo il campione testato. Prima dell'uso, ispezionare i guanti per verificare l'assenza di difetti o imperfezioni. Smettere adeguatamente qualsiasi quanto che presenti difetti Consultare le istruzioni allegate per indossare e togliere il prodotto. Solo monouso. Conservare in un luogo asciutto e fresco. Smettere in conformità alle disposizioni locali. Un elenco di sostanze note come causa di allergie può essere fornito su richiesta. **PER CONTATTARCI** - Per chiarimenti circa questo prodotto rivolgersi al produttore al numero 1-800-255-6401 (USA), +44(0) 1737 736000 (Europa), +603 7807 8210 (Asia Pacifico).

☞ Guantes estériles de nitrilo G3 Sterling™

- 12 pulg./30,5 cm de largo
- Pares específicos para cada mano
- Texturizados
- No fabricado con látex de goma natural
- Para entornos de sala blanca de esterilización crítica
- Sólo para uso industrial

AVISO: COMO MEDIDA DE SEGURIDAD, ESTE ENCARTO SE DEBE ENTREGAR O PONER A DISPOSICIÓN DE LOS USUARIOS DE ESTOS GUANTES Este es un producto de Categoría III PPE certificado según el Reglamento

REF G3 Sterile Sterling™ -

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

CE 0123 UK 0168

EAC TPTC 019/2011

AQL 1.5

EN ISO 374-1:2016+A1:2018/Type C



- ☞ Tested for Watertightness, Chemical Permeation and Chemical Degradation
- ☞ Testés pour l'imperméabilité, la perméation de produits chimiques et la dégradation chimique
- ☞ Sometidos a pruebas de estanqueidad, permeación química y degradación química
- ☞ Geprüft auf Wasserdichtigkeit, Permeation von chemischen Substanzen und chemische Abbaubarkeit
- ☞ Прошли испытання на водонепронцаємость, проницаємость для химических веществ и химическое разрушение
- ☞ Проійшли випробування на водонепроникність і захист від проникнення та стійність до хімічних речовин
- ☞ 水密性、化学物質の浸透、化学的劣化は試験済み

EN ISO 374-5:2016



VIRUS



- ☞ Single Use Only.
- ☞ Usage unique seulement
- ☞ Úseuse una sola vez
- ☞ Nur zur einmaligen Verwendung
- ☞ Тільки для одноразового применения
- ☞ Виключно для одноразового застосування
- ☞ 再使用禁止



- ☞ Protect from Heat and Radioactive Sources
- ☞ À protéger contre les sources de chaleur et radioactives
- ☞ Proteger contra fuentes de calor y radioactividad
- ☞ Vor Hitze und radioaktiven Strahlen schützen
- ☞ Беречь от нагрева и источников радиоактивного излучения
- ☞ Оберегати від нагрівання і джерел радіоактивного випромінювання
- ☞ 熱および放射線源は避けてください



- ☞ Keep Dry
- ☞ Conserver au sec
- ☞ Mantener secos
- ☞ Trocken halten
- ☞ Хранить в сухом месте
- ☞ Зберігати в сухому місці
- ☞ 湿気厳禁

G3 Sterile Sterling™ Nitrile Gloves

Permeation Test EN ISO 374-1:2016+A1:2018		Degradation Test EN ISO 374-4:2019	
☞ Chemical	Breakthrough Time (min.)	Performance Level	Performance Level %
Sodium Hydroxide 40% (K)	>480	Class 6	>60LT

EN ISO 21420:2020 Dexterity Classification = 5



Certificates available from www.kimtech.com/certificates

EU and UK Product Declarations of Conformity available at www.kimtech.eu

