

Kimtech™ G3 Sterile Sterling™ Nitrile Gloves

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



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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

Tallo.

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 BABT 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

		P	hysical Test D	ata**			
		Visual Defects				Elongation (%)	Tensile (MPa)
	Watertight	Critical Visual	Major	Minor	Dimensions	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/cm²
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

		Ext	ractable Ion Te	st Data**			
	Anions Results						
	Fluoride F	Chloride Cl ⁻	Nitrite N0 ₂	Bromide Br	Nitrate N0 ₃	Phosphate P0 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 Res	sults
	Sodium	Ammonium	Potassium	Magnesium	Calcium	Zinc	
	Na*	NH ₄ ⁺	K ⁺	Mg ⁺²	Ca ⁺²	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: Specification: BD

Endotoxin Units/ device

≤ 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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9×. 14 Fcb 2023

Review By:

(QA Sr. Manager)

FORM-21963/5



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 SADAO Amphur Sadad** SONGKHLA 90120 **THAILAND**

Order Information

Account	Number:
ANGERED BANKA	Number.

Synergy Health Sales Part Reference:

Customer Reference Number:

Product Description:

Validation Reference:

Ouantity Received:

Customer Minimum Specification kGy:

Customer Maximum Specification kGy:

Customer Unit Lot/Batch Number:

Other Process Details:

101195

1126466

4027021163

KIMTECH*G3,STERILE STERLING NITRILE

GLOVES.HAND SPECIFIC

0.0697 Rev02

93

25.0

50.0

SEE BELOW

Kimtech* G3, Sterile Sterling Nitrile Gloves, Hand

KC Code: 11821-40, 11822-40, 11823-40,

11824-40, 11825-40, 11826-40, 11827-

40,11828-40

Catalog

Lot No./Batch No.

Quantity

Number(s)

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

NOR AZWIN BT. YUSUF OA Executive Synergy Sterilisation (M) Sdn. Bhd



http://www.steris-ast.com

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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

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

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

WOR AZWIN BT. YUSUF OA Executive Synergy Sterilisation (M) Sdn. Bhd +60(0)44152111

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: September 161/67 Microbiologist

Report Reviewed By: QA Manager

SUMMARY

This study was undertaken in accordance with Method VD max ²⁵ 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 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 ± 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 cutout 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 :

5. Calculations

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

(Sample (counts/mL)-Blank (Counts/mL) x Extraction volume (mL) x DF Surface area (in cm²)

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

- 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 :

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/cm² 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/cm².

Case Label

G3 Sterile Sterling* **Nitrile Gloves**





30 x

10 = 300

- (EN) G3 Sterile Sterling* Nitrile Gloves
- ® G3 Sterling* Gants stériles en nitrile
- Guantes estériles de nitrilo G3 Sterling*
- © G3 Sterile Sterling* Nitrilhandschuhe
- G3 steriele Sterling[∗] nitril handschoenen
- G3 Guanti sterili in nitrile Sterling*
- ® G3 Стерильные нитриловые перчатки Sterling*
- Рукавички стерильні нітрилові G3 Sterling*
- P Luvas de nitrilo Sterling* estéreis G3
- ⑩ G3 멸균 Sterling* 니트릴 장갑
- ② G3无菌Sterling*丁腈手套
- ♨ G3滅菌Sterling*ニトリル手袋

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







11826 40

C€0123 點 0168 Ⅲ

LOT Lot Number

Номер партии 製造番号

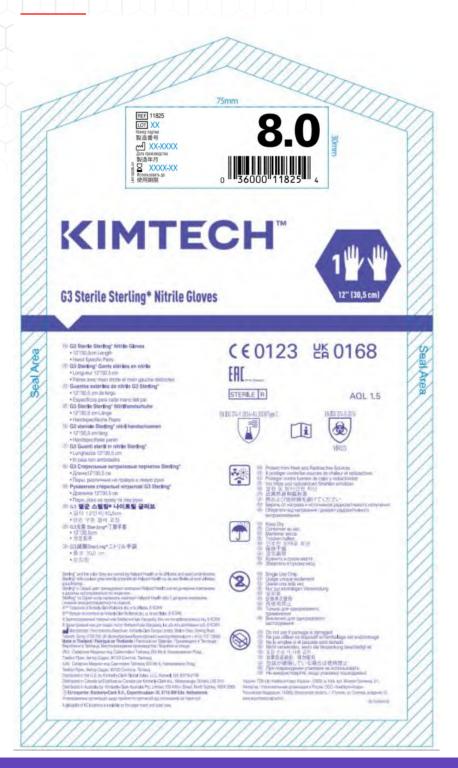
Date of Manufacturing Дата производства 製造年月

YY-MM **Expiration Date** Использовать до 使用期限

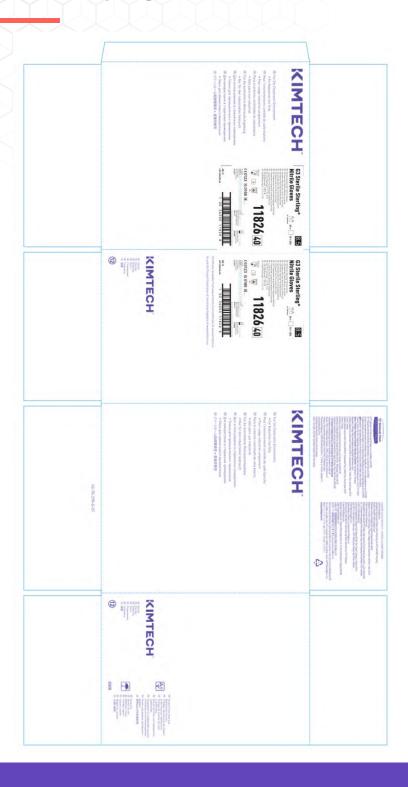
0 0 36000 11826

AQL 1.5 LM1182640OL-00

Sterile Pair Pouch



KDF Artwork



KIMTECH

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



G3 Sterile Sterling™ Nitrile Gloves

- 12"/30.5cm Length
- Hand Specific Pairs
- TexturedNot Made With Natural Rubber Latex

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

(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 tis 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 proportion. 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

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

- 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
 AVI UTILISATEURS DE CES GANTS OU ÊTRE À LEUR DISPOSITION.
 Il s'agit d'un EPI de catégorie III certifié conforme au Règlement (UE)

Il s'agit d'un EPI de categorie III certifie conforme au Reglement (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 valuée 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 prélevel so résultats peuvent être différents si le produit chimique est hespensent. dans un mélange. Les résultats peur le tel uniter les le directions si le production indique en tel 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 gue 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 (États-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

- 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

randiache entionimene Proben bestimmt und obzeint sich nur auf die geprüte 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 zu pruten, da sich die Bedinglungen 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 gefähltiche 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 begrüngsbeitzung sich Der Paderstänsprädischa unzufausten Jerschafelingungen. Faktor sein, der bei der Auswahl von chemikalenbeständigen 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 lagem. Gemäß den lokalen Bedingungen entsorgen. Eine Liste der Stoffe, die bekanntermaßen Allergien auslösen, kann auf Anfrage gelefert werden.

SO KONTAKTIEREN SIE UNS: Bei Fragen zu diesem Produkt rufen Sie bitte den Hersteller an unter der Nummer (US) 1-800-255-6401; (FILI) ±44(J) 1737 738007. (API) ±603 7807. 8210.

(EU) +44(0) 1737 736000; (AP) +603 7807 8210

G3 steriele Sterling™ nitril handschoenen

- 30.5cm/12 inch langHandspecifieke paren
- Getextureerd
- Niet gemaakt van natuurlijke rubberlatex
- Voor steriele kritische schone ruimtes

Alleen voor industrieel gebruik
WAARSCHUWING: DEZE BIJSLUITER DIENT ALS
VEILIGHEIDSMAATREGEL GEGEVEN TE WORDEN AAN OF TER
BESCHIKKING GESTELD TE WORDEN VAN DE GEBRUIKERS VAN DEZE

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 zuwere chemicaliën. De chemische weerstand is onder laboratoriumomstandigheden beoordeeld op grond van monsters. weerstand is onder laboratoriumomistandigheden 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 aanbevden 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 leten bet derventlijke okprijekte produkt vergeven verbedigene in de fivieringen in de fivieri auraan. Dij het geruik kulleri besche product vanwege veranderingen in de tysische leigen bet gevaaflijke chemische product vanwege veranderingen in de tysische eigenschappen. Bewegingen, blijven haken, wrijven, afbraak veroorzaakt door contact met het chemische producte tet. kunnen de werkellijke gebruiksduur aarlienlijk 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-Pacific) +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 industrial
 AWISO - 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
 certo escarza phimicha (cohizzi) e miscarzanicimi:

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 statta 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 siano idonei per l'uso previsto poiché le condizioni del luogo di lavoro possono differire dal tipo di lest a seconda della temperatura, abrasione e degradazione. Quando utilizzati, i quanti di protezione possono fornire meno resistenza ai proditti chimici periocolosi a causa di cambiamenti delle proprietà fisiche. Il tempo effettivo di utilizzo può essere ridotto significativamente a causa di movimenti, sifiacciamento, strofinamento o degradazione dovuti al contatto con prodotti chimici, ec. In caso di contatto con prodotti chimici corrosivi, il fattore più determinante da considerare nella scella 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 diffetti o imperfezioni. Smalfire adeguatamente qualsiasi guanto che presenti difetti Consultare le istruzioni allegate per indossare e togliere il prodotto. Solo monouso. Conservare in un luogo asciutto e fresco. Smalfire in conformità alle disposizioni locali. Un elenco di sostanze note come causa di allergie può essere fomito su richiesta. 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

- 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 ENCARTE SE DEBE ENTREGAR
O PONER A DISPOSICIÓN DE LOS USUÁRIOS 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 = 118248.0 = 11825

8.5 = 11826

9.0 = 11827

10.0 = 11828

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TPTC 019/2011

AQL 1.5

- ENISO 3741:2016;4A1:2018/Type (® 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 испытания на водонепроницаемость, проницаемость для химических веществ и химическое разрушение
 - 係 Пробили минитесного решего в палитесного разрушения
 係 Пробили випробування на водонепромикність і захист від проникнення та стійкість до хімічних речовин
 水密性、化学物質の浸透、化学的劣化は試験済み
- (B) Tested for Microorganism Hazards FN ISO 374-5:2016 ® Testé contre les risques de microorganismes





- Испытано на наличие опасных микроорганизмов
 Перевірено на наявність небезпечних мікроорганізмів
- ④ 危険化学物質および微生物に対する防護性を試験済み



- ® Single Use Only.
- ® Usage unique seulement
 Usese una sola vez
- ® Nur zur einmaligen Verwendung
 в Только для одноразового
- применения

 Виключно для одноразового



- ® Protect from Heat and Radioactive Sources
 À protéger contre les sources de chaleur et radioactives
- Proteger contra fuentes de calor y radiactividad
 Vor Hitze und radioaktiven Strahlen schützen
- Беречь от нагрева и источников радиоактивного излучения
 Оберігати від нагрівання і джерел радіоактивного



- ® Keep Dry
 Conserver au sec
- © Mantener secos © Trocken halten
- ® Хранить в сухом месте Зберігати в сухому місці

G3 Sterile Sterling™ Nitrile Gloves

0.0 0.0			
	Degradation Test		
	EN ISO 374-4:2019		
(III) Chemical	Breakthrough Time(min.)	Performance Level	Performance Level %
Sodium Hydroxide 40% (K)	>480	Class 6	-60.1

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

σχισίματα, τριβή, αποδόμηση που προκλήθηκε από επαφή με τη χημική ουσία κ.λπ. ενδέχεται να μειώσουν σημαντικά τον πραγματικό χρόνο χρήσης. Όσον αφορά στις διαβρωτικές χημικές ουσίες, η αποδόμηση είναι ο πιο σημαντικός πραγγοντας που πρέπει να λάβει κανείς υπόψη του κατά την επιλογή γαντιών ανθεκτικών στις χημικές ουσίες. Η αντίσταση διείσουσης έχει υπολογιστεί σε εργαστηριακές συνθήκες και σχετίζεται μόνο με το ελεγχόμενο είδος. Πριν από τη χρήση ελέγξτε τα γάντια για ελαττώματα ή ατέλειες. Απορρίψτε τυχόν γάντια που παρουσιάζουν ελάττωμα Ανατρέξτε στις συνημμένες οδηγίες φορέματος και αλλάγματος. Αποκλειστικά μίας χρήσης. Φυλάσσεται σε δροσερό και ξηρό χώρο. Απορρίψτε σύμφωνα με τους τοτικούς κανονισμούς. Ένας κατάλογος ουσών που είναι γνωστό ότι προκαλούν αλλεργίες, μπορεί να παρασχεθεί κατ'αίτηση. ΕΠΙΚΟΙΜΩΝΙΑ: Αν έχετε ερωτήσεις σχετικά με το παρόν προϊόν, καλέστε τον κατασκευαστή στον αριθμό (Η.Π.Α.) 1-800-255-6401 (Ε.Ε.)

G3 Steril Sterling™ Nitril Eldiven

+44(0) 1737 736000 (Ασία-Ειρηνικός) +603 7807 8210

- 12"/30.5 cm Uzunluğunda Ele Özel Çift
- Dokulu

 Doğal Kauçuk Lateksten Üretilmemiştir
 Obğal Kauçuk Lateksten Üretilmemiştir
 Steril Kritik Temiz Oda Ortamları içindir
 Yalnızça Endüstriyel Kullarım İçindir
 NEMIL: BU BILGİLENDİRME EKİ GÜVENLİK ÖNLEMİ OLARAK KULLANICIYA ELDEN VERİLMELİ YA DA KULLANICININ ERİŞİMİNE SUNULMALIDIR.
BU ürün (AB) 2016/425 AET sayılı Yönetmelik'e göre sertifikalandırılmış Kategori III KKD (Kişisel Koruyucu Donanımı Ürünüdür. Risk: Eldivenler kimyasallara (Sıçrama) ve mikroorganizmalara karşı koruma sağlar.
Bu bilgi, çalışma yerlerindeki gerçek koruma süresini ve karışmlar ile saf kimyasallar arasındaki farklığıy qınıstmamaktadır. Kimyasal direnç, laboratıvar koşulan altında valurca ayucı çinden alınan pumunlerile Gicilimistir ve sadçec test edilen yalnızca avuç içinden alınan numuneler ile ölçülmüştür ve sadece test edilen kimyasala ilişkindir. Kimyasal bir karışımda kullanıtlyorsa, farklı olabilir. Bozunum sonuçları, kimyasal maruziyeti sonrasında delinme direncini göstermektedir. sonuçlan, kımıyasal maruziyeti sonrasında delinme direncini göstermektedir. Eldivenlerin istenen kullanım için uygun olup olmadığını kontrol etmeniz önerilir, çünkü çalışma yerindeki koşullar sıcaklık, aşımına ve bozunmaya bağlı olarak tip testinden farklı olabilir. Koruyucu eldivenler kullanlıdığında, fiziksel özelliklarde meydana gelen değişiklikler nedeniyle tehlikeli kimyasallara karşı daha az direnç gösterebilir. Hareketler, delinmeler, sürtünme, kimyasal temastan kaynaklarıan bozunmalar gerçek kullanım süresini büyük ölçüde azaltabilir. Aşındınçı kimyasallar için kimyasallara kularım süresini büyük ölçüde azaladınır. Agrioride kirilyesileli in kirilyasalara dirençli eldiven seçiminde bozunma en önemli faktördür. Nüfuz etmeye karşı direnç laboratuvar koşulları altında ölçülmüştür ve yalnızca test edilen numuneye ilişkindir. Kullanmadan önce eldivenlerde herhangi bir kusur veya eksiklik olup olmadığını kontrol edir. Kusurlu eldivenleri atın Ekli takma ve çıkarma talimatlarına bakın. Tek kullanım içindir. Serin ve kuru ortamda saklayın Yerel düzenlemelere göre bertaraf edin Alerjiye neden olduğu bilinen maddelerin listesi talep üzerine temin edilebilir. BİZİ ARAYIN: Bu ürün hakkındaki her türlü sorunuz için 1-800-255-6401 (ABD), +44(0) 1737 736000 (Avrupa), +603 7807 8210 (Asya) numaralı telefondan imalatçıya ulaşabilirsiniz.

② G3 无菌 Sterling™ 丁腈手套

◎ G3 멸균 스털링* 나이트릴 글러브

- S us 글로 스클팅* 나이트!
 길이 12inch/30.5cm
 알손 한 쌍
 텍스쳐 처리
 천연고무 라텍스 성분 없음
 중요 멸균 클린룸용
 공업용

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$^{ ext{\tiny TM}}$ ถุงมือในไตร Sterling $^{ ext{\tiny TM}}$ ปลอดเชื้อ G3

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- ขึ้นลาย
- ไม่ได้ผลิตขึ้นจากน้ำยางธรรมชาติ
- สำหรับสภาพห้องสะอาดปลอดเชื้อขั้นสูง
- สำหรับใช้ในอตสาหกรรมเท่านั้น

หมายเหตุ: เอ[๊]กสารเพิ่มเดิมนี้ควรได้รับการจัดทำหรือจัดเตรียมให้แก่ผู้ใช้ถุงมือเหล่านี้สำ หรับใช้เป็นข้อควรระวังเพื่อความปลอดภัย

น์คือผลิตภัณฑ์ประเภท III PPE ที่ได้รับการรับรองตามระเบียบข้อบังคับ (EU) 2016/425 EEC ความเสียง: ถุงมือช่วยป้องกันสารเคมี (กระเด็น) และจุลินทรีย์

ข้อมูลนี้ไม่ได้บ่งบอกถึงระยะเวลาการป้องกันจริงในสถานที่ทำงาน

และความแตกต่างระหว่างสารผสมและสารเคมีบริสุทธิ์

ความต้านทานสารเคมีได้รับการประเมินภายใต้สภาพห้องปฏิบัติการจากตัวอย่างที่ได้จากปาล์มเ ท่านั้น และสัมพันธ์กับสารเคมีที่ทดสอบเท่านั้น ผลลัพธ์อาจแตกต่างออกไป หากมีการใช้สารเคมีในสารผสม

ผลการเสื่อมสลายแสดงว่าความด้านทานต่อการเจาะทะลุมีการเปลี่ยนแปลงหลังจากลัมผัสกับสา รเคมีที่ระบุ แนะนำให้ตรวจสอบว่าถุงมือมีความเหมาะสมตามวัตถุประสงค์ของการใช้งาน เนื่องจากสภาวะในสถานที่ทำงานอาจแตกต่างจากประเภทที่ทดสอบ ทั้งนี้ขึ้นอยู่กับอุณหภูมิ

การขีดข่วน และการเสื่อมสภาพ เมื่อใช้แล้ว ถูงมือป้องกันอาจมีความต้านทานสารเคมีอันตรายน้อยลง

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Donning Gloves



Check seal is undamaged, Open walle



Place hand in, align fingers to the holes Open and close fingers whilst pulling glove up.



Start with the second glove. Place the fingers in-between fold and nouch. Lift fingers to reveal opening.



Pull up the cuff evenly by moving fingers round beading.





Once first glove is on



Lift glove out of the pouch and reneat sten 3



Pull up the cuff of the other hand. Secure it evenly up the arm. For double donning restart process at step 1.

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Doffing Gloves







Ball the glove up and hold in your other gloved hand.



Carefully pull the glove off your hand.



Carefully pull the glove off your hand, turning it inside-out,



Slide your ungloved finger into the opening of the other glove.



Discard appropriately

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