



SHIELDskin XTREME™

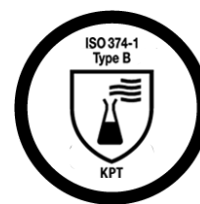
A REVOLUTION IN GLOVE TECHNOLOGY

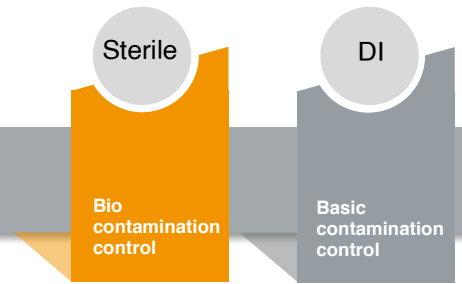
Sterile

BIO
CONTAMINATION CONTROL

SHIELDskin XTREME™

Sterile ORANGE NITRILE™ 300 DI





- ⇒ Powder-free single DI washed hand-specific standard length (300 mm / 11.8") sterile nitrile/neoprene cleanroom gloves.
- ⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.
- ⇒ Fully compliant to the latest PPE Protective gloves EU norms against chemicals, micro-organisms and viruses.

| DESCRIPTION | |
|-------------|---|
| Formulation | Nitrile and neoprene synthetic rubber (<i>acrylonitrile butadiene and polychloroprene</i>). |
| Design | Orange, hand-specific, beaded cuff, textured palm and fingers. |
| Packaging | 1 pair per PE peel pouch - 20 pouches per double sealed PE bag - 10 double sealed PE bags per tied carton liner - 1 tied carton liner per carton = 200 pairs. |

| SIZES | 5.5 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9 | 10 |
|-------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Codes | 69 6551 | 69 6552 | 69 6553 | 69 6554 | 69 6555 | 69 6556 | 69 6557 | 69 6558 | 69 6559 |

| STANDARDS | |
|---------------------------|--|
| CE/UKCA registration | PPE Category III (Complex Design) - Regulation (EU) 2016/425. CE Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND. UKCA Notified Body No 0120: SGS United Kingdom Ltd, Ellesmere port - UNITED-KINGDOM. |
| EU PPE norms | ISO 21420:2020, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B. |
| EU MDR norms ¹ | EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009. |
| USA standards | ASTM D3767-03 (2020), ASTM D573-04 (2019), ASTM D412-16, ASTM D6978-05 (2019) and IEST-RP-CC005.4 (2013). |
| Other standards | ISO 11137-2:2015, ISO 10993-10:2021. |

¹With reference to Regulation (EU) 2017/425 for Medical Devices

| QUALITY | |
|-------------------|--|
| Quality assurance | Production management in accordance with ISO 9001:2015 and ISO 13485:2016. Environmental management systems in accordance with ISO 14001:2015. |
| Technology | uniSHIELD™ single-walled protection to offer an ideal compromise between comfort and protection. Compatible with sterile processing environments due to paperless packaging and multiple post leaching of gloves (single washed in deionised water). |

| DOCUMENTATION | |
|---------------------------------|--|
| Declaration of conformity | These documents can be freely downloaded from the product page on our website: www.shieldscientific.com . For easy access, scan the QR code. To access CoC and Col, you need to be registered. Please contact us at info@shieldscientific.com or call your SHIELD Scientific representative. |
| EU type examination certificate | |
| User's instructions | |
| Certificate of conformance | |
| Certificate of irradiation | |



PHYSICAL PROPERTIES



| NOMINAL THICKNESS | mm ² | mil | Norm |
|-------------------|-----------------|-----|----------------------|
| ⇒ Finger | 0.15 | 5.9 | ASTM D3767-03 (2020) |
| ⇒ Palm | 0.14 | 5.5 | |
| ⇒ Cuff | 0.09 | 3.5 | |

² Thickness (+/- 0.03 mm)

| LENGTH | Minimum | Typical | Norm |
|--|------------------|----------------|----------------|
| ⇒ From middle finger tip to edge of cuff | ≥ 300 mm / 11.8" | 305 mm / 12.0" | ISO 21420:2020 |

| STRENGTH PROPERTIES | Force at break (spec.) | | Ultimate elongation (spec.) | Force at break (typical) | Norm |
|---------------------|------------------------|--------|-----------------------------|--------------------------|--|
| ⇒ Before aging | ≥ 6.0N | 14 MPa | ≥ 500% | 12.0N | EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16 |
| ⇒ After aging | ≥ 6.0N | 14 MPa | ≥ 400% | 11.0N | |

| FREEDOM FROM HOLES | Performance | Norm |
|----------------------------------|-------------------------------|----------------|
| ⇒ Acceptable Quality Level (AQL) | < 0.65 ³ - Level 3 | ISO 374-2:2019 |

³ AQL as defined per ISO 2859-1:1999 for sampling by attributes.

| RISKS | Description | Norm |
|-----------------|--|---|
| Micro-organisms | 1000 ml water test. Performance level 3, AQL < 0.65 (inspection level G1). | ISO 374-2:2019 |
| Viruses | Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B. | ISO 374-5:2016 |
| Chemicals | <u>Performance</u> : Type B (KPT). <u>Permeation</u> : Extensively tested. Online chemical resistance guide on www.shieldscientific.com . <u>Degradation</u> : Tested for determination of resistance to degradation by chemicals. | ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018 ISO 374-4:2019 |
| Cytotoxic | Tested for permeation to potentially hazardous cancer chemotherapy drugs under conditions of continuous contact. | ASTM D6978-05 (2019) |

CLEANLINESS PROPERTIES

| PARTICLES | Specification | Typical value | Test method |
|-----------------------------------|---------------------------|-----------------|-----------------|
| Particles/cm ² ≥ 0.5µm | < 3,000 particles (spec.) | 1,000 particles | IEST-RP-CC005.4 |

| EXTRACTABLES (ION) | Specification (µg/cm ²) | Typical value (µg/cm ²) | Test method |
|------------------------------|-------------------------------------|-------------------------------------|-----------------|
| Ammonium (NH ₄) | 0.050 | 0.015 | IEST-RP-CC005.4 |
| Bromide (Br) | 0.030 | < 0.008 | |
| Calcium (Ca) | 0.500 | 0.300 | |
| Chloride (Cl) | 0.400 | 0.100 | |
| Fluoride (F) | 0.010 | < 0.008 | |
| Magnesium (Mg) | 0.010 | < 0.008 | |
| Nitrate (NO ₃) | 0.200 | 0.090 | |
| Nitrite (NO ₂) | 0.050 | < 0.008 | |
| Phosphate (PO ₄) | 0.050 | < 0.008 | |
| Potassium (K) | 0.050 | 0.020 | |
| Sodium (Na) | 0.050 | 0.008 | |
| Sulphate (SO ₄) | 0.050 | 0.008 | |

| EXTRA TESTS | Description | Test method |
|-------------|---|-------------------|
| Sterility | Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10 ⁻⁶ (ISO 11137-2:2015). | |
| Endotoxins | Low Endotoxin content at < 20 EU/pair demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test. | EN 455-3:2015 |
| NVR | Maximum 30 µg/g. | IEST-RP-CC005.4 |
| FTIR | Silicone free and non-detectable levels of amide and DOP. | IEST-RP-CC005.4 |
| ESD | Tested for electrostatic properties. | EN 1149-1/2/3 & 5 |

| ALLERGIES | |
|--------------------|---|
| Bio-Compatibility | Demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2021. |
| Accelerators | Accelerator-free to minimize the risk of allergic contact dermatitis (also known as Type IV, delayed hypersensitivity or chemical allergy). |
| Chemical Allergens | Non-detectable levels using aqueous solution extraction (Phosphate buffered solution) and High Performance Liquid Chromatography (HPLC) assay method for quantitative analysis. |
| Latex Protein | Latex-free. |