SHIELDskin XTREME™

A REVOLUTION IN GLOVE TECHNOLOGY

**Sterile**

BIO
CONTAMINATION CONTROL

# SHIELDskin XTREME™

## Sterile Latex 300 DI



PPE
Personal Protective Equipment
Category III
REGULATION
(EU) 2016/425

CE
0598

ISO 374-1
Type B
KPT

ISO 374-5:2016
Level 3
VIRUS

LATEX

Sterile

Bio contamination control

DI

Basic contamination control

⇒ Powder-free single DI washed hand-specific standard length (300 mm / 11.8") sterile natural rubber latex 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 | Natural rubber latex (*Hevea Brasiliensis*). |
| Design | Natural colour, hand-specific, beaded cuff, textured palm and fingers. |
| Packaging | 1 pair per PE peel pouch - 20 pouches per sealed poly bag - 10 poly bags per PE bag per carton. |

| SIZES | 5.5 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|
| Codes | 69 5551 | 69 5552 | 69 5553 | 69 5554 | 69 5555 | 69 5556 | 69 5557 | 69 5558 | 69 5559 |

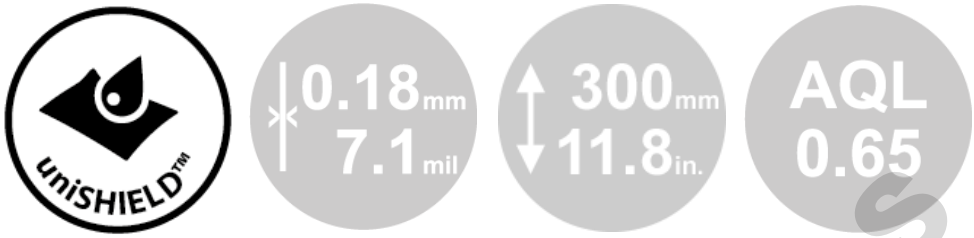
| STANDARDS | |
|---|---|
| CE registration | PPE Category III (Complex Design) - Regulation (EU) 2016/425.<br>Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND. |
| EU PPE norms | ISO 21420:2020, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and 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 D5712-15 and IEST-RP-CC005.4 (2013). |
| Other standards | ISO 11137-2:2015, ISO 10993-10:2010. |

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

| QUALITY | |
|---|---|
| Quality assurance | Production management in accordance with ISO 9001:2015 and ISO 13485:2016.<br>Environmental management systems in accordance with ISO 14001:2015. |
| Technology | uniSHIELD™ single-walled protection to offer an ideal compromise between comfort and protection.<br>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.<br><br>For easy access, scan the QR code. |
| EU type examination certificate | |
| User's instructions | |
| Certificate of conformance | To access CoC and CoI, you need to be registered.<br><br>Please contact us at info@shieldscientific.com or call your SHIELD Scientific representative. |
| Certificate of irradiation | |

# PHYSICAL PROPERTIES




| NOMINAL THICKNESS | mm² | mil | Norm |
|---|---|---|---|
| ⇒ Finger | 0.20 | 7.9 | ASTM D3767-03 (2020) |
| ⇒ Palm | 0.18 | 7.1 | |
| ⇒ Cuff | 0.12 | 4.7 | |

[2] *Thickness (+/- 0.03 mm)*

| LENGTH | Minimum | Typical | Norm |
|---|---|---|---|
| ⇒ From middle finger tip to edge of cuff | ≥ 290 mm / 11.4" | 300 mm / 11.8" | ISO 21420:2020 |

| STRENGTH PROPERTIES | Force at break (spec.) | | Ultimate elongation (spec.) | Force at break (typical) | Norm |
|---|---|---|---|---|---|
| ⇒ Before aging | ≥ 9.0N | 18 MPa | ≥ 700% | 14.0N | EN 455-2:2015<br>ASTM D573-04 (2019)<br>& ASTM D412-16 |
| ⇒ After aging | ≥ 6.0N | 14 MPa | ≥ 500% | 12.0N | |

| 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.<br>Performance level 3, AQL < 0.65<br>(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 | Performance: Type B (KPT).<br>Permeation: Extensively tested. Online chemical resistance guide on www.shieldscientific.com.<br>Degradation: Tested for determination of resistance to degradation by chemicals. | ISO 374-1:2016+A1:2018<br>EN 16523-1:2015+A1:2018<br><br>ISO 374-4:2019 |

# CLEANLINESS PROPERTIES

| PARTICLES | Specification | Typical value | Test method |
|---|---|---|---|
| Particles/cm² ≥ 0.5$\mu$m | < 3,000 particles (spec.) | 1,100 particles | IEST-RP-CC005.4 |

| EXTRACTABLES (ION) | Specification (µg/cm²) | Typical value (µg/cm²) | Test method |
|---|---|---|---|
| Ammonium ($NH_4$) | 0.100 | 0.030 | IEST-RP-CC005.4 |
| Bromide (Br) | 0.030 | < 0.008 | |
| Calcium (Ca) | 0.500 | 0.250 | |
| Chloride (Cl) | 0.750 | 0.380 | |
| Fluoride (F) | 0.010 | < 0.008 | |
| Magnesium (Mg) | 0.010 | < 0.008 | |
| Nitrate ($NO_3$) | 0.400 | 0.150 | |
| Nitrite ($NO_2$) | 0.050 | < 0.008 | |
| Phosphate ($PO_4$) | 0.050 | < 0.008 | |
| Potassium (K) | 0.050 | 0.020 | |
| Sodium (Na) | 0.050 | 0.011 | |
| Sulphate ($SO_4$) | 0.100 | 0.015 | |

| 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 $\mu$g/g. | IEST-RP-CC005.4 |
| FTIR | Silicone free and non-detectable levels of amide and DOP. | IEST-RP-CC005.4 |

| ALLERGIES | |
|---|---|
| Bio-Compatibility | Demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2010. |
| Accelerators | Free of Thiazoles and Thiurams. These chemical accelerators are excluded from the manufacturing process. |
| 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 | ≤ 50 $\mu$g/g as per Modified Lowry Method (EN 455-3:2015/ASTM D5712-15). Typical: ≤ 30 $\mu$g/g as per Modified Lowry Method. |



SHIELD Scientific
compliance comfort protection

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