# SHIELDskin XTREME™

A REVOLUTION IN GLOVE TECHNOLOGY

DI

BASIC
CONTAMINATION
CONTROL

## TECHNICAL INFORMATION

## SHIELDskin XTREME™
White Nitrile 300 DI

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

MDD Medical Device Class I DIRECTIVE 93/42/EEC

CE 0123

ISO 374-1 Type B KPT

ISO 374-5:2016 Level 2 VIRUS

⇒ Powder-free single DI washed ambidextrous standard length (300 mm / 11.8") non-sterile nitrile cleanroom gloves.

⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.

⇒ Medical Device Class 1 (MDD) according to the Directive 93/42/EEC.

⇒ Fully compliant to the latest PPE Protective gloves EU norms against chemicals, micro-organisms and viruses.

| DESCRIPTION | |
|---|---|
| FORMULATION | Nitrile synthetic rubber (acrylonitrile butadiene). |
| DESIGN | White, ambidextrous, beaded cuff, textured fingertips. |
| PACKAGING | 100 gloves per PE bag - 10 bags per polybag - 1 polybag per carton. |

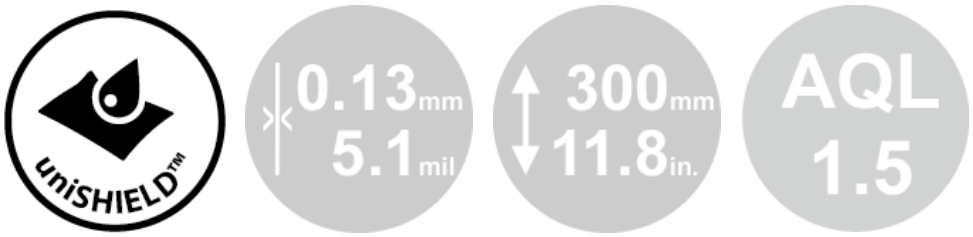
| SIZES | 6/XS | 7/S | 8/M | 9/L | 10/XL | 11/XXL |
|---|---|---|---|---|---|---|
| CODES | 69 8451 | 69 8452 | 69 8453 | 69 8454 | 69 8455 | 69 8456 |

| STANDARDS | |
|---|---|
| CE REGISTRATION | PPE Category III (Complex Design) - Regulation (EU) 2016/425.<br>Notified Body No 0123: TÜV Produkt Service - Germany.<br>MDD Class 1 - Directive 93/42/EEC. |
| EU PPE NORMS | EN 420:2003+A1:2009, ISO 374-1:2016+A1:2018, EN 374-2:2014, ISO 374-4:2013, ISO 374-5:2016, EN 16523-1:2015+A:2018 and ISO 16604:2004 Procedure B. |
| EU MDD NORMS | EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009. |
| USA STANDARDS | ASTM D3767-03 (2014), ASTM D573-04 (2015), ASTM D412-16, ASTM D6978-05 (2019) and IEST-RP-CC005.4 (2013). |
| OTHER STANDARDS | EN 1149-1/2/3 & 5, ISO 10993-10:2010. |

| QUALITY | |
|---|---|
| QUALITY ASSURANCE | Production management in accordance with ISO 9001:2015 and ISO 13485:2016. |
| TECHNOLOGY | uniSHIELD™ single-walled protection to offer an ideal compromise between comfort and protection.<br>Synthetic soft polymer based on Skin Nitrile™ technology. Compatible with clean 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>For an easy access, scan the QR code. |
| EU TYPE EXAMINATION CERTIFICATE | |
| PRODUCT INSERT | |
| CERTIFICATE OF CONFORMANCE | To access CoC, you need to be registered. Please contact us at info@shieldscientific.com or call your SHIELD Scientific representative. |

# PHYSICAL PROPERTIES




| NOMINAL THICKNESS | mm[1] | mil | Norm |
|---|---|---|---|
| ⇒ Finger | 0.15 | 5.9 | ASTM D3767-03 (2014) |
| ⇒ Palm | 0.13 | 5.1 | |
| ⇒ Cuff | 0.10 | 3.9 | |

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

| LENGTH | Minimum | Typical | Norm |
|---|---|---|---|
| ⇒ From middle finger tip to edge of cuff | ≥ 285 mm / 11.2" | 300 mm / 11.8" | EN 420:2003+A1:2009 |

| STRENGTH PROPERTIES | Force at break (spec.) | | Ultimate elongation (spec.) | Force at break (typical) | Norm |
|---|---|---|---|---|---|
| ⇒ Before aging | ≥ 6.0N | 14 Mpa | ≥ 500% | 9.0N | EN 455-2:2015<br>ASTM D573-04 (2015)<br>& ASTM D412-16 |
| ⇒ After aging | ≥ 6.0N | 14 Mpa | ≥ 400% | 8.0N | |

| FREEDOM FROM HOLES | Performance | Norm |
|---|---|---|
| ⇒ Acceptable Quality Level (AQL) | < 1.5[2]- Level 2 | EN 374-2:2014<br>EN 455-1:2000 |

[2] *AQL as defined per ISO 2859-1:1999 for sampling by attributes.*

| RISKS | Description | Norm |
|---|---|---|
| MICRO-ORGANISMS | 1000 ml water test.<br>Performance level 2, AQL < 1.5 (inspection level G1). | EN 374-2:2014 |
| 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+1:2018<br><br>EN 374-4:2013 |
| CYTOTOXIC | Tested for permeation by potentially hazardous cancer chemotherapy drugs under conditions of continuous contact. | ASTM D6978-05 (2019) |

# CLEANLINESS PROPERTIES

| PARTICLES | Specification | Typical value | Test method |
|---|---|---|---|
| Particles/cm² ≥ 0.5µm | <3 000 particles | 2 300 particles | IEST-RP-CC005.4 |

| EXTRACTABLES (ION) | Specification (µg/cm²) | Typical value (µg/cm²) | Test method |
|---|---|---|---|
| Ammonium ($NH_4$) | 0.050 | <0.008 | IEST-RP-CC005.4 |
| Bromide (Br) | 0.030 | <0.008 | |
| Calcium (Ca) | 1.000 | 0.700 | |
| Chloride (Cl) | 0.600 | 0.300 | |
| Fluoride (F) | 0.010 | <0.008 | |
| Magnesium (Mg) | 0.010 | <0.008 | |
| Nitrate ($NO_3$) | 0.600 | 0.230 | |
| Nitrite ($NO_2$) | 0.050 | <0.008 | |
| Phosphate ($PO_4$) | 0.050 | <0.008 | |
| Potassium (K) | 0.150 | 0.050 | |
| Sodium (Na) | 0.150 | 0.040 | |
| Sulphate ($SO_4$) | 0.200 | 0.130 | |

| EXTRA TESTS | Description | Test method |
|---|---|---|
| NVR | Maximum 30 mg/g. | IEST-RP-CC005.4 |
| FTIR | Non-detectable levels of silicone, 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 10993-10:2010. |
| ACCELERATORS | Free of Thiurams and Thiazoles. These chemicals 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 | Latex-free. |

SHIELD Scientific
compliance comfort protection

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