

# SHIELDskin XTREME™

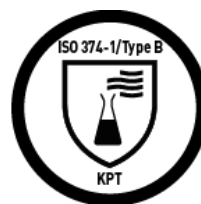
A REVOLUTION IN GLOVE TECHNOLOGY

## DI+

HIGH  
CONTAMINATION CONTROL

# SHIELDskin XTREME™

## Eco Nitrile 300 DI+





DI+

High  
contamination  
control

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

| DESCRIPTION |                                                                                                                                      |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------|
| Formulation | Nitrile synthetic rubber ( <i>Acrylonitrile butadiene</i> ).                                                                         |
| Design      | White, ambidextrous, beaded cuff, textured fingertips.                                                                               |
| Packaging   | 100 gloves per double sealed PE bag - 15 double sealed PE bags per tied carton liner - 1 tied carton liner per carton = 1500 gloves. |

| SIZES | 6/XS    | 7/S     | 8/M     | 9/L     | 10/XL   | 11/XXL  |
|-------|---------|---------|---------|---------|---------|---------|
| Codes | 68 8651 | 68 8652 | 68 8653 | 68 8654 | 68 8655 | 68 8656 |

| STANDARDS                 |                                                                                                                                                                                                                                                                                                                                                    |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CE/UKCA registration      | PPE Category III (Complex Design) - Regulation (EU) 2016/425.<br>CE Notified Body No 2797: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, Unit 4.2, 1066 EP Amsterdam, The Netherlands.<br>UKCA Notified Body No 0086: BSI Assurance UK Ltd, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom. |
| EU PPE norms              | ISO 21420:2020+A1:2022, 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 <sup>1</sup> | 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 and IEST-RP-CC005.4 (2013).                                                                                                                                                                                                                                                                |
| Other standards           | EN 1149-1/2/3 & 5, ISO 10993-10:2021.                                                                                                                                                                                                                                                                                                              |

<sup>1</sup>With reference to Regulation (EU) 2017/745 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 clean processing environments due to paperless packaging and multiple post leaching of gloves (triple washed in deionised water). |

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

# PHYSICAL PROPERTIES



| NOMINAL THICKNESS | mm <sup>2</sup> | mil | Norm                 |
|-------------------|-----------------|-----|----------------------|
| ⇒ Finger          | 0.15            | 5.9 | ASTM D3767-03 (2020) |
| ⇒ Palm            | 0.10            | 3.9 |                      |
| ⇒ Cuff            | 0.07            | 2.8 |                      |

<sup>2</sup> Thickness (+/- 0.03 mm)

| LENGTH                                   | Minimum          | Typical        | Norm                   |
|------------------------------------------|------------------|----------------|------------------------|
| ⇒ From middle finger tip to edge of cuff | ≥ 285 mm / 11.2" | 300 mm / 11.8" | ISO 21420:2020+A1:2022 |

| STRENGTH PROPERTIES | Force at break (spec.) |        | Ultimate elongation (spec.) | Force at break (typical) | Norm                                                   |
|---------------------|------------------------|--------|-----------------------------|--------------------------|--------------------------------------------------------|
| ⇒ Before aging      | ≥ 6.0N                 | 14 MPa | ≥ 500%                      | 10.0N                    | EN 455-2:2015<br>ASTM D573-04 (2019)<br>& ASTM D412-16 |
| ⇒ After aging       | ≥ 6.0N                 | 14 MPa | ≥ 400%                      | 8.0N                     |                                                        |

| FREEDOM FROM HOLES               | Performance                     | Norm           |
|----------------------------------|---------------------------------|----------------|
| ⇒ Acceptable Quality Level (AQL) | < 1.5 <sup>3</sup> G1 - Level 2 | ISO 374-2:2019 |

<sup>3</sup> 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).                                                                                                                                                                                                           | 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).<br><u>Permeation</u> : Extensively tested. Online chemical resistance guide on <a href="http://www.shieldscientific.com">www.shieldscientific.com</a> .<br><u>Degradation</u> : 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/cm <sup>2</sup> ≥ 0.5µm | < 1,200 particles | 1,100 particles | IENT-RP-CC005.4 |

| EXTRACTABLES (ION)           | Specification (µg/cm <sup>2</sup> ) | Typical value (µg/cm <sup>2</sup> ) | Test method     |
|------------------------------|-------------------------------------|-------------------------------------|-----------------|
| Ammonium (NH <sub>4</sub> )  | 0.050                               | 0.015                               | IENT-RP-CC005.4 |
| Bromide (Br)                 | 0.030                               | < 0.008                             |                 |
| Calcium (Ca)                 | 0.300                               | 0.190                               |                 |
| Chloride (Cl)                | 0.200                               | 0.110                               |                 |
| Fluoride (F)                 | 0.010                               | < 0.008                             |                 |
| Magnesium (Mg)               | 0.010                               | < 0.008                             |                 |
| Nitrate (NO <sub>3</sub> )   | 0.200                               | 0.100                               |                 |
| Nitrite (NO <sub>2</sub> )   | 0.050                               | < 0.008                             |                 |
| Phosphate (PO <sub>4</sub> ) | 0.050                               | < 0.008                             |                 |
| Potassium (K)                | 0.050                               | 0.020                               |                 |
| Sodium (Na)                  | 0.050                               | 0.010                               |                 |
| Sulphate (SO <sub>4</sub> )  | 0.050                               | 0.010                               |                 |
| Zinc (Zn)                    | 0.050                               | 0.030                               |                 |

| EXTRA TESTS | Description                                               | Test method       |
|-------------|-----------------------------------------------------------|-------------------|
| NVR         | Maximum 10 µg/cm <sup>2</sup> .                           | IENT-RP-CC005.4   |
| FTIR        | Silicone free and non-detectable levels of amide and DOP. | IENT-RP-CC005.4   |
| ESD         | Tested for electrostatic properties.                      | EN 1149-1/2/3 & 5 |

| ALLERGIES          |                                                                                                                                                                                 |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Bio-Compatibility  | Demonstrated by skin irritation and sensitisation tests in accordance with ISO 10993-10:2021.                                                                                   |
| 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.                                                                                                                                                                     |