



# SHIELDskin XTREME™

## Sterile ORANGE NITRILE™ 300 DI

Powder Free cleanroom laundered Hand-specific Sterile 30 cm Nitrile Gloves

PPE Category III (Complex Design) according to Council Directive 89/686/EEC

Fully compliant to the latest PPE norms – EN 374:2003 “Protective gloves against chemicals and micro-organisms”

### PRODUCT INFORMATION

| Size | Catalogue Numbers | Applicable Norms with Pictograms  |             |  |
|------|-------------------|---|-------------|--|
| 5.5  | 69 6551           | EN 374:2003   | EN 374:2003 |  |
| 6.0  | 69 6552           |   | <br>Level 3 |  |
| 6.5  | 69 6553           |   |             |  |
| 7.0  | 69 6554           | EN 420:2003 + A1:2009   |             |  |
| 7.5  | 69 6555           | Also meets or exceeds EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 & EN 455-4:2009 relating to Council Directive 93/42/EEC for Medical Devices |             |  |
| 8.0  | 69 6556           |   |             |  |
| 8.5  | 69 6557           |   |             |  |
| 9.0  | 69 6558           |   |             |  |
| 10.0 | 69 6559           |   |             |  |

\* SGS UK Ltd (Notified Body No: 0120), Unit 202B Worle Parkway, Weston-super-Mare, BS22 6WA, United Kingdom

**Material:** Synthetic soft nitrile polymer (Acrylonitrile Butadiene) with blend of polychloroprene, based on Skin Nitrile™ technology. Contains no natural rubber latex.

**Design:** Orange, hand-specific, beaded cuff, with textured palm and fingers.

**Packaging:** Packaging designed to comply with sterile processing environments. Gloves pair packed in a sealed polyethylene pouch. Twenty (20) pouches per sealed (double) poly bag. Ten (10) poly bags per double walled shipping case. Total of 200 pairs per outer case.

### PHYSICAL PROPERTIES

| Characteristics    | Value                 | Test Method |
|--------------------|-----------------------|-------------|
| Freedom from holes | 0.65 AQL <sup>1</sup> | EN 374:2003 |

<sup>1</sup> AQL as defined per ISO 2859 for sampling by attributes

| Tensile Properties        | Tensile Strength(min) Typical |      | Ultimate Elongation | EN 455-2:2015, ASTM D573-04(2015) and ASTM D412-15a |
|---------------------------|-------------------------------|------|---------------------|---|
|                           |                               |      |                     |   |
| - Before Aging            | 6.0N,min.                     | 7.0N | 500%, min.          |   |
| - After Accelerated Aging | 6.0N,min.                     | 8.0N | 400%, min..         |   |

## PHYSICAL PROPERTIES (Continued)

| Characteristics     | Value          |                |     | Test Method             |
|---------------------|----------------|----------------|-----|-------------------------|
| <b>Dimensional</b>  | Measured Point | mm             | mil |                         |
| - Nominal Thickness | Middle Finger  | 0.15           | 5.9 | ASTM D3767-03(2014)     |
|                     | Palm           | 0.12           | 4.7 |                         |
|                     | Cuff           | 0.09           | 3.5 |                         |
| - Length            | 300mm, min.    | 305mm, typical |     | EN 420: 2003 + A1: 2009 |

## Hand Circumference

|                       |     |     |     |     |     |     |     |     |     |                       |
|-----------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----------------------|
| Nominal circumference | 5.5 | 6   | 6.5 | 7   | 7.5 | 8   | 8.5 | 9   | 10  | EN 420:2003 + A1:2009 |
| (mm)                  | 140 | 152 | 165 | 178 | 191 | 203 | 216 | 229 | 254 |                       |

## CLEANLINESS PROPERTIES

| Particles |                            |               |           |               | Test Method     |
|-----------|----------------------------|---------------|-----------|---------------|-----------------|
|           |                            | Specification |           | Typical value |                 |
| Particles | Per cm <sup>2</sup> ≥0.5µm | <3.000        | particles | 2.500         | particles       |
|           |                            |               |           |               | IEST-RP-CC005.4 |

| Extractables |                 |               |                    |               |                    | Test Method     |
|--------------|-----------------|---------------|--------------------|---------------|--------------------|-----------------|
| Ion          |                 | Specification |                    | Typical value |                    | IEST-RP-CC005.4 |
| Ammonium     | NH <sub>4</sub> | 0.150         | ug/cm <sup>2</sup> | 0.030         | ug/cm <sup>2</sup> |                 |
| Bromide      | Br              | 0.150         | ug/cm <sup>2</sup> | 0.050         | ug/cm <sup>2</sup> |                 |
| Calcium      | Ca              | 1.000         | ug/cm <sup>2</sup> | 0.800         | ug/cm <sup>2</sup> |                 |
| Chloride     | Cl              | 0.600         | ug/cm <sup>2</sup> | 0.450         | ug/cm <sup>2</sup> |                 |
| Fluoride     | F               | 0.090         | ug/cm <sup>2</sup> | 0.050         | ug/cm <sup>2</sup> |                 |
| Magnesium    | Mg              | 0.150         | ug/cm <sup>2</sup> | 0.050         | ug/cm <sup>2</sup> |                 |
| Nitrate      | NO <sub>3</sub> | 0.600         | ug/cm <sup>2</sup> | 0.450         | ug/cm <sup>2</sup> |                 |
| Potassium    | K               | 0.150         | ug/cm <sup>2</sup> | 0.100         | ug/cm <sup>2</sup> |                 |
| Sodium       | Na              | 0.150         | ug/cm <sup>2</sup> | 0.050         | ug/cm <sup>2</sup> |                 |
| Sulphate     | SO <sub>4</sub> | 0.600         | ug/cm <sup>2</sup> | 0.450         | ug/cm <sup>2</sup> |                 |

## ADDITIONAL DATA

- **Biocompatibility** demonstrated by Modified Buehler and Primary Skin Irritation Tests.
- **Non detectable levels of chemical allergens** using aqueous solution extraction (Phosphate buffered solution) and High Performance Liquid Chromatography (HPLC) assay method for quantitative analysis.
- **Accelerator-free** to minimize the risk of Allergic Contact Dermatitis (also known as Type IV, Delayed Hypersensitivity or Chemical Allergy).
- **Powder free** to minimize the potential consequences of powder-borne dermatitis. Residual powder content is 1.0 mg/glove (typical) with a limit of 2.0 mg/glove (ISO 21171:2006 "Medical gloves - Determination of removable surface powder").
- **Micro-organism and virus resistant** - passes highest level of micro-organism resistance per EN 374-2:2014 (Performance level 3, AQL <0.65 and inspection level G1 according to 1000ml water test) and passes viral penetration test using Phi-X 174 bacteriophage (ISO 16604:2004 Procedure B & ASTM F1671-97b).
- **Compatible with sterile processing environments** due to paperless packaging and multiple post leaching of gloves.
- **Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10<sup>-6</sup>**, in accordance with guidelines detailed in EN ISO 11137-2:2015 "Sterilization of Healthcare Products - Radiation".
- **Low Endotoxin content at <20 EU/pair (EN 455-3:2015)** demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test.
- **FTIR:** non detectable levels of silicone, amide and DOP (IEST-RP-CC005.4).
- **NVR:** maximum 30mg/g (IEST-RP-CC005.4).
- **Tested for electrostatic properties** according to EN 1149-1/2/3 & 5.
- **Extensively tested for chemical permeation** according to EN 16523-1:2015 (please refer to chemical resistance guide on website - [www.shieldscientific.com/public/chemical-resistance-guide](http://www.shieldscientific.com/public/chemical-resistance-guide)).

## QUALITY SYSTEMS

- Manufactured in accordance with ISO 9001:2015 and ISO 13485:2016.

"SHIELDskin™, A revolution in Glove Technology"



[www.shieldscientific.com](http://www.shieldscientific.com)

SHIELDskin XTREME™, ORANGE NITRILE™ and the COLOUR ORANGE technology are trademarks of SHIELD Scientific © 2007 Copyright SHIELD Scientific B.V. All Rights reserved  
Dr. Willem Dreeslaan 1 • 6721 ND Bennekom • The Netherlands - Phone +31 (0)317 700 202 • Fax +31 (0)318 503 742 • E-mail: [Info@shieldscientific.com](mailto:Info@shieldscientific.com)