



Powder Free cleanroom laundered Ambidextrous Non-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 | | |
|----------------------------|-------------------|---|--|------------------|
| Extra Small (XS/6) | 69 6451 | EN 374:2003 | EN 374:2003 Level 2 | 0120* |
| Small (S/7) | 69 6452 | | | |
| Medium (M/8) | 69 6453 | | | |
| Large (L/9) | 69 6454 | | | |
| Extra Large (XL/10) | 69 6455 | EN 420:2003 + A1:2009 | | |
| Extra Extra Large (XXL/11) | 69 6456 | 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 | | |

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

Material: Proprietary multi-polymer formulation (Acrylonitrile Butadiene with blend of polychloroprene), based on twinSHIELD™ technology. Contains no natural rubber latex.

Design: Double barrier protection afforded by orange outer layer combined with white inner-lining. Ambidextrous, beaded cuff and with textured fingertips.

Packaging: One hundred gloves (100) per inner poly bag. Packaging designed to comply with cleanroom environments processes. Gloves are flat-packed. Ten (10) poly bags per inner bag. Packed per 10 poly bags in a double-walled shipping case. 1000 gloves per case.

PHYSICAL PROPERTIES

| Characteristics | Value | Test Method |
|--------------------|----------------------|-------------|
| Freedom from holes | 1.5 AQL ¹ | EN 374:2003 |

¹ AQL as defined per ISO 2859 for sampling by attributes

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

PHYSICAL PROPERTIES (Continued)

| Characteristics | | Value | | Test Method |
|---------------------|----------------|----------------|-----|-----------------------|
| Dimensional | Measured Point | mm | mil | |
| - Nominal Thickness | Middle Finger | 0.17 | 6.6 | ASTM D3767-03(2014) |
| | Palm | 0.14 | 5.5 | |
| | Cuff | 0.10 | 4.0 | |
| - Length | 290mm, min. | 300mm, typical | | EN 420:2003 + A1:2009 |

Palm Width

| | XS/6 | S/7 | M/8 | L/9 | XL/10 | |
|--------------------|------|-----|-----|-----|-------|--------------|
| Nominal Width (mm) | ≤80 | 85 | 95 | 105 | ≥110 | EN455-2:2015 |

Hand Circumference

| | XS/6 | S/7 | M/8 | L/9 | XL/10 | |
|----------------------------|------|-----|-----|-----|-------|-----------------------|
| Nominal Circumference (mm) | 152 | 178 | 203 | 229 | 254 | EN 420:2003 + A1:2009 |

CLEANLINESS PROPERTIES

| Particles | | Test Method |
|--------------------------------------|---------------|-----------------|
| Size | Nominal value | |
| Particles per cm ² ≥0.5µm | <3.000 | IEST-RP-CC005.4 |

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

IEST-RP-CC005.4

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** - micro-organism resistant per EN 374-2:2014 (Performance level 2, AQL <1.5 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).
- **FTIR:** non detectable levels of silicone, amide and DOP (IEST-RP-CC005.4).
- **Surface Resistivity:** $10^8 - 10^{10} \Omega/\text{sq.}$ (ASTM D257-14).
- **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).

QUALITY SYSTEMS

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

“SHIELDskin™, A revolution in Glove Technology”



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