SHIELD Scientific
compliance comfort protection

SHIELDskin™

ORANGE NITRILE™ 300 Sterile

Powder Free Extra Length Ambidextrous 30 cm Sterile Nitrile Gloves with Textured Fingertips

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)	67 6351	EN 374:2003 	EN 374:2003  Level 3	CE 0120*
Small (S/7)	67 6352			
Medium (M/8)	67 6353			
Large (L/9)	67 6354	EN 420:2003 + A1:2009		
Extra Large (XL/10)	67 6355	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: Packaging designed to comply with sterile processing environments. Gloves pair packed in a sealed polyethylene pouch. Twenty (20) pouches per sealed polyethylene bag. Eight (8) polyethylene bags per double-walled shipping case. Total of 160 pairs per outer case.

PHYSICAL PROPERTIES

Characteristics	Value	Test Method
Freedom from holes	<0.65 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.	

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	290, min.		300mm, typical	EN 420:2003 + A1:2009

Palm Widths

- Nominal Width (mm)	XS/6	S/7	M/8	L/9	XL/10	EN 455-2:2015
	≤80	85	95	105	≥110	

Hand Circumference

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

ADDITIONAL DATA

- **Biocompatibility** demonstrated by 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-X174 bacteriophage (ISO 16604:2004 Procedure B & ASTM F1671-97b).
- **Compatible with sterile processing environments** due to paperless packaging and multiple post-leaching of gloves. Typical particle levels (per cm^2 and at > 0.5 µm) are <3.000 particles.
- **Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10^{-6},** 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.
- **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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www.shieldscientific.com

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