SHIELD Scientific
compliance comfort protection

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  Level 3	CE 0120*
6.0	69 6552			
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[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	0.15	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 $cm^2 \geq 0.5\mu m$	<3.000	particles	2.500	particles	IEST-RP-CC005.4

Extractables						Test Method
Ion		Specification		Typical value		
Ammonium	NH_4	0.150	ug/cm^2	0.030	ug/cm^2	IEST-RP-CC005.4
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	

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^{-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.
- **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).

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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