SHIELDskin XTREME™ Sterile White Nitrile 330 DI+

Powder Free Extra Length DI washed Hand-specific Sterile 33cm 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 8761	EN 374:2003 	EN 374:2003  Level 3	CE 0123*
6.0	69 8762			
6.5	69 8763			
7.0	69 8764	EN 420:2003 + A1:2009		
7.5	69 8765	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 8766			
8.5	69 8767			
9.0	69 8768			
10	69 8769			

- TÜV Produkt Service, (Notified Body No:0123), Ridlestrasse 3, D-80339 München, Germany

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

Design: White, 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	0.10	4.0	
- Length	330mm, min.		335mm, 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 $cm^2 \geq 0.5\mu m$	<1.200 particles	900 particles	IEST-RP-CC005.4

Extractables						Test Method
Ion		Specification		Typical value		
Ammonium	NH_4	0.100	ug/cm^2	0.070	ug/cm^2	IEST-RP-CC005.4
Bromide	Br	0.200	ug/cm^2	0.140	ug/cm^2	
Calcium	Ca	0.350	ug/cm^2	0.250	ug/cm^2	
Chloride	Cl	0.350	ug/cm^2	0.250	ug/cm^2	
Copper	Cu	0.050	ug/cm^2	0.030	ug/cm^2	
Fluoride	F	0.200	ug/cm^2	0.140	ug/cm^2	
Iron	Fe	0.050	ug/cm^2	0.030	ug/cm^2	
Magnesium	Mg	0.350	ug/cm^2	0.250	ug/cm^2	
Nitrate	NO_3	0.030	ug/cm^2	0.020	ug/cm^2	
Potassium	K	0.100	ug/cm^2	0.070	ug/cm^2	
Sodium	Na	0.100	ug/cm^2	0.070	ug/cm^2	
Sulphate	SO_4	0.100	ug/cm^2	0.070	ug/cm^2	
Zinc	Zn	0.350	ug/cm^2	0.250	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.
- **Free of Thiurams and Thiazoles** – these chemical accelerators are excluded from the manufacturing process.
- **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.
- **NVR:** maximum 30mg/g (IEST-RP-CC005.4).
- **FTIR**: non detectable levels of silicone, amide and DOP (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"

SHIELD Scientific
compliance comfort protection

www.shieldscientific.com

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