



SHIELDskin XTREME™

White Nitrile 300 DI

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 8451	EN 374:2003 	EN 374:2003 Level 2	
Small (S/7)	69 8452			
Medium (M/8)	69 8453			
Large (L/9)	69 8454	EN 420:2003 + A1:2009		
Extra Large (XL/10)	69 8455			
Extra Extra Large (XXL/11)	69 8456	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		

* TÜV Produkt Service, 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, ambidextrous, beaded cuff, with textured finger tips.

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 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 D 412-15a
- 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	0.13	5.1	
	Cuff	0.10	3.9	
- Length	285mm, min.	300mm, typical		EN 420:2003 + A1:2009

Palm Width

	XS/6	S/7	M/8	L/9	XL/10	XXL/11	
Nominal Width (mm)	≤80	85	95	105	115	≥120	EN 455-2:2015

Hand Circumference

	XS/6	S/7	M/8	L/9	XL/10	XXL/11	
Nominal Circumference (mm)	152	178	203	229	254	279	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.
- **Free of Thiurams and Dithiocarbamates** - 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** - 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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