



**SHIELDskin XTREME™**  
A REVOLUTION IN GLOVE TECHNOLOGY

**Sterile**

BIO  
CONTAMINATION CONTROL

# SHIELDskin XTREME™

## Sterile White Nitrile 330 DI+





Sterile

Bio contamination control

DI+

High contamination control

- ⇒ Powder-free triple DI washed hand-specific extra length (330 mm / 13.0") sterile nitrile cleanroom gloves.
- ⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.
- ⇒ Fully compliant to the latest PPE Protective gloves EU norms against chemicals, micro-organisms and viruses.

DESCRIPTION	
Formulation	Nitrile synthetic rubber ( <i>acrylonitrile butadiene</i> ).
Design	White, hand-specific, beaded cuff, textured palm and fingers.
Packaging	1 pair per PE peel pouch - 20 pouches per double sealed PE bag - 10 double sealed PE bags per tied carton liner - 1 tied carton liner per carton = 200 pairs.

SIZES	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9	10
Codes	69 8761	69 8762	69 8763	69 8764	69 8765	69 8766	69 8767	69 8768	69 8769

STANDARDS	
CE registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0123: TÜV Produkt Service, Germany.
EU PPE norms	ISO 21420:2020, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
EU MDR norms <sup>1</sup>	EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009.
USA standards	ASTM D3767-03 (2020), ASTM D573-04 (2019), ASTM D412-16, ASTM D6978-05 (2019) and IEST-RP-CC005.4 (2013).
Other standards	ISO 11137-2:2015, ISO 10993-10:2021.

<sup>1</sup>With reference to Regulation (EU) 2017/425 for Medical Devices

QUALITY	
Quality assurance	Production management in accordance with ISO 9001:2015 and ISO 13485:2016. Environmental management systems in accordance with ISO 14001:2015.
Technology	uniSHIELD™ single-walled protection to offer an ideal compromise between comfort and protection. Compatible with sterile processing environments due to paperless packaging and multiple post leaching of gloves (triple washed in deionised water).

DOCUMENTATION	
Declaration of conformity	These documents can be freely downloaded from the product page on our website: <a href="http://www.shieldscientific.com">www.shieldscientific.com</a> .
EU type examination certificate	For easy access, scan the QR code.
User's instructions	
Certificate of conformance	To access CoC and CoI, you need to be registered.
Certificate of irradiation	Please contact us at <a href="mailto:info@shieldscientific.com">info@shieldscientific.com</a> or call your SHIELD Scientific representative.



# PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm <sup>2</sup>	mil	Norm
⇒ Finger	0.17	6.7	ASTM D3767-03 (2020)
⇒ Palm	0.14	5.5	
⇒ Cuff	0.10	3.9	

<sup>2</sup> Thickness (+/- 0.03 mm)

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 330 mm / 13.0"	335 mm / 13.2"	ISO 21420:2020

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 6.0N	14 MPa	≥ 500%	9.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 MPa	≥ 400%	8.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 0.65 <sup>3</sup> - Level 3	ISO 374-2:2019

<sup>3</sup> AQL as defined per ISO 2859-1:1999 for sampling by attributes.

RISKS	Description	Norm
Micro-organisms	1000 ml water test. Performance level 3, AQL < 0.65 (inspection level G1).	ISO 374-2:2019
Viruses	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
Chemicals	<u>Performance</u> : Type B (JKP). <u>Permeation</u> : Extensively tested. Online chemical resistance guide on <a href="http://www.shieldscientific.com">www.shieldscientific.com</a> . <u>Degradation</u> : Tested for determination of resistance to degradation by chemicals.	ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018  ISO 374-4:2019
Cytotoxic	Tested for permeation to potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	ASTM D6978-05 (2019)

# CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm <sup>2</sup> ≥ 0.5µm	< 1,200 particles	1,000 particles	IEST-RP-CC005.4

EXTRACTABLES (ION)	Specification (µg/cm <sup>2</sup> )	Typical value (µg/cm <sup>2</sup> )	Test method
Ammonium (NH <sub>4</sub> )	0.050	< 0.008	IEST-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.350	0.260	
Chloride (Cl)	0.350	0.260	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.050	0.009	
Nitrate (NO <sub>3</sub> )	0.200	0.060	
Nitrite (NO <sub>2</sub> )	0.050	< 0.008	
Phosphate (PO <sub>4</sub> )	0.050	< 0.008	
Potassium (K)	0.100	0.040	
Sodium (Na)	0.100	0.040	
Sulphate (SO <sub>4</sub> )	0.100	0.050	

EXTRA TESTS	Description	Test method
Sterility	Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10 <sup>-6</sup> (ISO 11137-2:2015).	
Endotoxins	Low Endotoxin content at < 20 EU/pair demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test.	EN 455-3:2015
NVR	Maximum 30 µg/g.	IEST-RP-CC005.4
FTIR	Silicone free and non-detectable levels of amide and DOP.	IEST-RP-CC005.4
ESD	Tested for electrostatic properties.	EN 1149-1/2/3 & 5
DNase and RNase contamination	DNase and RNase free.	MO BIO Certification

ALLERGIES	
Bio-Compatibility	Demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2021.
Accelerators	Free of Thiazoles and Thiurams. These chemical accelerators are excluded from the manufacturing process.
Chemical Allergens	Non-detectable levels using aqueous solution extraction (Phosphate buffered solution) and High Performance Liquid Chromatography (HPLC) assay method for quantitative analysis.
Latex Protein	Latex-free.