

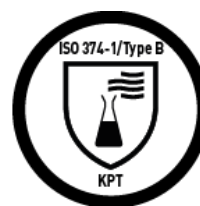
SHIELDskin XTREME™
A REVOLUTION IN GLOVE TECHNOLOGY

Sterile

BIO
CONTAMINATION CONTROL

SHIELDskin XTREME™

Sterile White Nitrile 600 DI+





Sterile

DI+

Bio
contamination
control

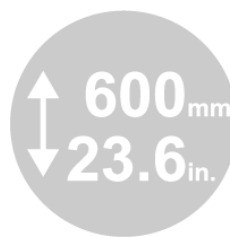
High
contamination
control

- ⇒ Powder-free triple DI washed hand-specific extra length (600 mm / 23.6") sterile nitrile cleanroom gloves.
- ⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.
- ⇒ Fully compliant to the latest EU PPE norms relating to protective gloves against chemicals, micro-organisms and viruses.

DESCRIPTION									
Formulation	Synthetic soft nitrile polymer (<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 - 5 double sealed PE bags per tied carton liner - 1 tied carton liner per carton = 100 pairs.								
SIZES	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9	10
Codes	69 8781	69 8782	69 8783	69 8784	69 8785	69 8786	69 8787	69 8788	69 8789
STANDARDS									
CE/UKCA registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. CE Notified Body No 2797: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, Unit 4.2, 1066 EP Amsterdam, The Netherlands. UKCA Notified Body No 0086: BSI Assurance UK Ltd, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.								
EU PPE norms	ISO 21420:2020+A1:2022, 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 ¹	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 and IEST-RP-CC005.4 (2013).								
Other standards	ISO 11137-2:2015, ISO 10993-10:2021.								
¹ With reference to Regulation (EU) 2017/745 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: www.shieldscientific.com .								
EU type examination certificate	For easy access, scan the QR code.								
User's instructions									
Certificate of conformance	To access CoC and Col, you need to be registered.								
Certificate of irradiation	Please contact us at info@shieldscientific.com or call your SHIELD Scientific representative.								



PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm ²	mil	Norm
⇒ Finger	0.20	7.9	ASTM D3767-03 (2020)
⇒ Palm	0.17	6.7	
⇒ Cuff	0.11	4.3	

² Thickness (+/- 0.03 mm)

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 580 mm / 22.8"	600 mm / 23.6"	ISO 21420:2020+A1:2022

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 6.0N	14 MPa	≥ 500%	11.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 MPa	≥ 400%	9.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 0.65 ³ G1 - Level 3	ISO 374-2:2019

³ 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 ⁴	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
Chemicals ⁴	<u>Performance</u> : Type B (KPT). <u>Permeation</u> : Extensively tested. Online chemical resistance guide on www.shieldscientific.com . <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

⁴ For PPER compliance, > 40 cm gloves are palm and cuff tested for permeation, degradation and viral penetration.

CLEANLINESS PROPERTIES

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

EXTRACTABLES (ION)	Specification (µg/cm ²)	Typical value (µg/cm ²)	Test method
Ammonium (NH ₄)	0.050	0.015	IENT-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.350	0.200	
Chloride (Cl)	0.200	0.090	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.010	< 0.008	
Nitrate (NO ₃)	0.050	0.020	
Nitrite (NO ₂)	0.030	< 0.008	
Phosphate (PO ₄)	0.030	< 0.008	
Potassium (K)	0.050	0.020	
Sodium (Na)	0.050	0.011	
Sulphate (SO ₄)	0.050	0.008	

EXTRA TESTS	Description	Test method
Sterility	Terminally sterilised by gamma irradiation to Sterility Assurance Level (SAL) of 10 ⁻⁶ (ISO 11137-2:2015).	EN 455-3:2015
Endotoxins	Low Endotoxin content at < 20 EU/pair demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic chromogenic test.	
NVR	Maximum 10 µg/cm ² .	IENT-RP-CC005.4
FTIR	Silicone free and non-detectable levels of amide and DOP.	IENT-RP-CC005.4

ALLERGIES	
Bio-Compatibility	Demonstrated by skin irritation and sensitisation 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.