SHIELDskin XTREME™
A REVOLUTION IN GLOVE TECHNOLOGY

Sterile
BIO
CONTAMINATION CONTROL

SHIELDskin XTREME™
Sterile White Nitrile 600 DI+

PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425

UK CA 0120

CE 0598

ISO 374-1 Type B KPT

ISO 374-5:2016 Level 3 VIRUS

Sterile

Bio contamination control

DI+

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 (*Acrylonitrile Butadiene*).
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

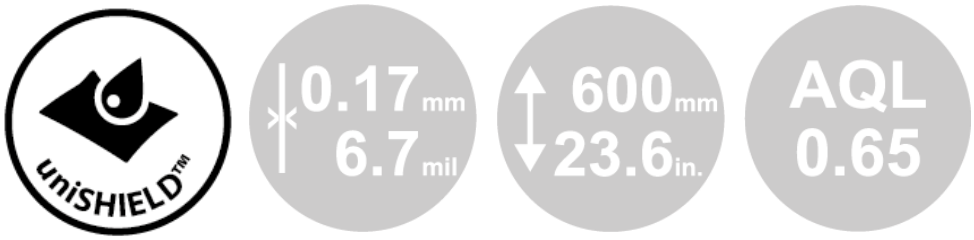
STANDARDS	
CE/UKCA registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. CE Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND. UKCA Notified Body No 0120: SGS United Kingdom Ltd, Ellesmere port - UNITED-KINGDOM.
EU PPE norms	ISO 21420:2020, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
EU MDR norms[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) 2017/425 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: www.shieldscientific.com. For easy access, scan the QR code.
EU type examination certificate	
User's instructions	
Certificate of conformance	To access CoC and CoI, you need to be registered. Please contact us at info@shieldscientific.com or call your SHIELD Scientific representative.
Certificate of irradiation	

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

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] - 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]	Performance: Type B (KPT). Permeation: Extensively tested. Online chemical resistance guide on www.shieldscientific.com. Degradation: 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/cm² ≥ 0.5µm	< 1,200 particles	1,000 particles	IEST-RP-CC005.4

EXTRACTABLES (ION)	Specification (µg/cm²)	Typical value (µg/cm²)	Test method
Ammonium (NH_4)	0.050	0.015	IEST-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)	0.030	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 sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10^{-6} (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

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.

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