SHIELDskin XTREME™

A REVOLUTION IN GLOVE TECHNOLOGY

DI+

HIGH
CONTAMINATION CONTROL

SHIELDskin XTREME™

White Nitrile 400 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 2
VIRUS

TECHNICAL INFORMATION

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DI+

High contamination control

⇒ Powder-free triple DI washed ambidextrous extra length (400 mm / 15.7") non-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 (*acrylonitrile butadiene*).
Design	White, ambidextrous, beaded cuff, textured palm and fingers.
Packaging	100 gloves per double sealed PE bag - 10 double sealed PE bags per tied carton liner - 1 tied carton liner per carton = 1000 gloves.

SIZES	6/XS	7/S	8/M	9/L	10/XL	11/XXL
Codes	69 8671	69 8672	69 8673	69 8674	69 8675	69 8676

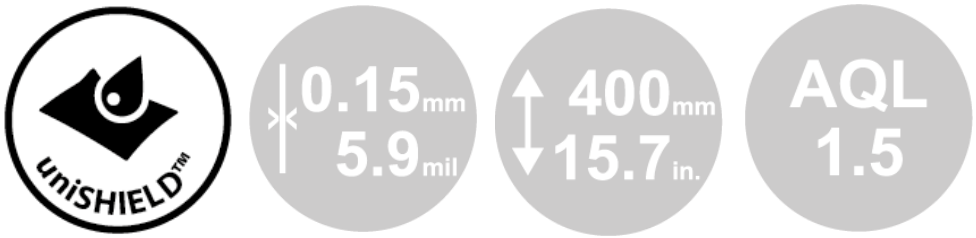
STANDARDS	
CE/UKCA registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. CE Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND. UKCA Notified Body No 0120: SGS United Kingdom Ltd, Ellesmere port - UNITED-KINGDOM.
EU PPE norms	ISO 21420:2020+A1:2022, ISO 374-1:2016+A1:2018, ISO 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, ASTM D6978-05 (2019) and IEST-RP-CC005.4 (2013).
Other standards	EN 1149-1/2/3 & 5, 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 clean 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, you need to be registered. 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	0.15	5.9	
⇒ Cuff	0.10	3.9	

[2] *Thickness (+/- 0.03 mm)*

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 385 mm / 15.2"	400 mm / 15.7"	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%	10.0N	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)	< 1.5[3] - Level 2	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 2, AQL < 1.5 (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
Cytotoxic	Tested for permeation by potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	ASTM D6978-05 (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	0.017	IEST-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.200	0.160	
Chloride (Cl)	0.200	0.110	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.010	< 0.008	
Nitrate (NO_3)	0.200	0.130	
Nitrite (NO_2)	0.050	< 0.008	
Phosphate (PO_4)	0.050	< 0.008	
Potassium (K)	0.050	0.020	
Sodium (Na)	0.050	0.020	
Sulphate (SO_4)	0.050	0.020	

EXTRA TESTS	Description	Test method
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

ALLERGIES	
Bio-Compatibility	Demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2021.
Accelerators	Free of Thiurams and Thiazoles. These chemicals 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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compliance comfort protection
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