SHIELDskin XTREME™

Sterile White Nitrile 400 DI+

DOMINIQUE DUTSCHER SAS

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

CE 2797

UK CA 0086

ISO 374-1/Type B KPT

ISO 374-5:2016 VIRUS

Sterile

Bio contamination control

DI+

High contamination control

⇒ Powder-free triple DI washed hand-specific extra length (400 mm / 15.7") 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, hand-specific, beaded cuff, textured palm and fingers.
Packaging	1 pair per PE peel pouch - 20 pouches per double sealed PE bag - 8 double sealed PE bags per tied carton liner - 1 tied carton liner per carton = 160 pairs.

SIZES	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9	10
Codes	69 8771	69 8772	69 8773	69 8774	69 8775	69 8776	69 8777	69 8778	69 8779

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, ASTM D6978-05 (2019) 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. 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	

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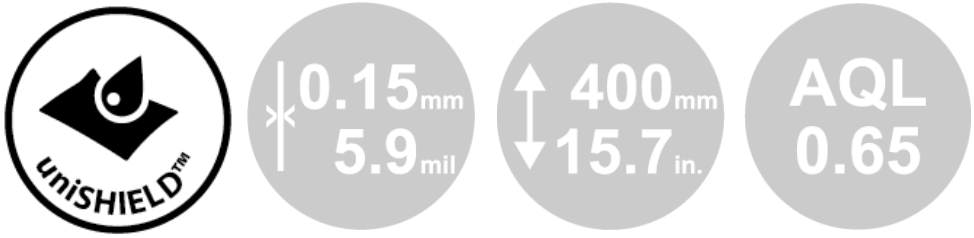
PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[2]	mil	Norm
⇒ Finger	0.18	7.1	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	≥ 400 mm / 15.7"	405 mm / 15.9"	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)	< 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]	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 to 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.*

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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	0.018	IEST-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.500	0.250	
Chloride (Cl)	0.200	0.110	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.010	< 0.008	
Nitrate (NO_3)	0.200	0.050	
Nitrite (NO_2)	0.050	< 0.008	
Phosphate (PO_4)	0.050	< 0.008	
Potassium (K)	0.050	0.023	
Sodium (Na)	0.050	0.012	
Sulphate (SO_4)	0.050	0.015	

EXTRA TESTS	Description	Test method
Sterility	Terminally sterilised 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 chromogenic test.	EN 455-3:2015
NVR	Maximum 10 µg/cm².	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 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.

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