SHIELDskin XTREME™

A REVOLUTION IN GLOVE TECHNOLOGY

Sterile

BIO

CONTAMINATION CONTROL

SHIELDskin XTREME™

Sterile ORANGE NITRILE™ 300 DI

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

CE 0598

ISO 374-1 Type B KPT

ISO 374-5:2016 Level 3 VIRUS

Sterile

Bio contamination control

DI

Basic contamination control

⇒ Powder-free single DI washed hand-specific standard length (300 mm / 11.8") sterile nitrile/ neoprene 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 and neoprene synthetic rubber (*acrylonitrile butadiene and polychloroprene*).
Design	Orange, hand-specific, beaded cuff, textured palm and fingers.
Packaging	1 pair per PE peel pouch - 20 pouches per sealed poly bag - 10 poly bags per PE bag per carton.

SIZES	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9	10
Codes	69 6551	69 6552	69 6553	69 6554	69 6555	69 6556	69 6557	69 6558	69 6559

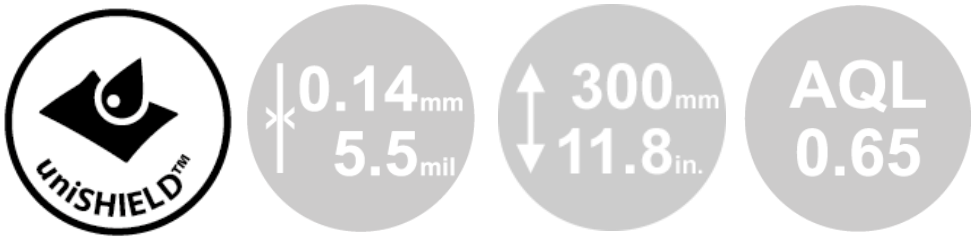
STANDARDS	
CE registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND.
EU PPE norms	ISO 21420:2020, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
EU MDR norms[1]	EN 455-1:2000, 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 10993-10:2010.

[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.
Technology	uniSHIELD™ single-walled protection to offer an ideal compromise between comfort and protection. Synthetic soft polymer, based on Skin Nitrile™ technology with a blend of polychloroprene. Compatible with sterile processing environments due to paperless packaging and multiple post leaching of gloves (single 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 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	0.15	5.9	ASTM D3767-03 (2020)
⇒ Palm	0.14	5.5	
⇒ Cuff	0.09	3.5	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 300 mm / 11.8"	305 mm / 12.0"	ISO 21420:2020

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 6.0N	14 MPa	≥ 500%	12.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 MPa	≥ 400%	11.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 0.65[3] - Level 3	ISO 374-2:2019 EN 455-1:2000

[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	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
Chemicals	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)

CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm² ≥ 0.5μm	< 3,000 particles (spec.)	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)	0.500	0.300	
Chloride (Cl)	0.400	0.100	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.010	< 0.008	
Nitrate (NO_3)	0.200	0.090	
Nitrite (NO_2)	0.050	< 0.008	
Phosphate (PO_4)	0.050	< 0.008	
Potassium (K)	0.050	0.020	
Sodium (Na)	0.050	0.008	
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	Non-detectable levels of silicone, 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 10993-10:2010.
Accelerators	Accelerator-free to minimize the risk of allergic contact dermatitis (also known as Type IV, delayed hypersensitivity or chemical allergy).
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.

SHIELD Scientific
compliance comfort protection

Dr. Willem Dreeslaan 1 ● 6721 ND Bennekom ● The Netherlands
Phone +31 (0)317 700 202 ● Fax +31 (0)318 503 742
E-mail: Info@shieldscientific.com
www.shieldscientific.com

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