

SHIELDskin™

ORANGE NITRILE™ 300 sterile





- ⇒ Powder-free ambidextrous extra length (300 mm / 11.8") sterile nitrile/neoprene protective 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	Nitrile and neoprene synthetic rubber (<i>Acrylonitrile butadiene and polychloroprene</i>).
Design	Orange, ambidextrous, beaded cuff, textured fingertips.
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	6/XS	7/S	8/M	9/L	10/XL	11/XXL
Codes	67 6351	67 6352	67 6353	67 6354	67 6355	67 6356

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, EN 421:2010, 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 21171:2006, ISO 11137-2:2015, ISO 10993-10:2021.

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	twinSHIELD™ double-walled protection to offer a stronger glove and to reduce risk of pinholes. Two colours: orange to make it easier to select according to the risk, combined with a soft and comfortable white interior.

DOCUMENTATION	
Declaration of conformity	These documents can be freely downloaded from the product page on our website: www.shieldscientific.com .
EU type examination certificate	
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	0.19	7.5	ASTM D3767-03 (2020)
⇒ Palm	0.14	5.5	
⇒ Cuff	0.10	3.9	

²Thickness (+/- 0.03 mm)

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 290 mm / 11.4"	300 mm / 11.8"	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)	< 0.25 ³ G1 - Level 3	ISO 374-2:2019

³AQL as defined per ISO 2859-1:1999 for sampling by attributes.

RISKS	Description	Norm
Micro-organisms	1000 ml water test. Performance level 3, AQL < 0.25 (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	<u>Performance</u> : Type B (JKPT). <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
Cytotoxic	Tested for permeation to potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	ASTM D6978-05 (2019)
Radioactivity	Protection from radioactive contamination.	EN 421:2010

CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm ² ≥ 0.5µm	< 3,000 particles (spec.)	2,200 particles	IENT-RP-CC005.4

EXTRACTABLES (ION)	Specification (µg/cm ²)	Typical value (µg/cm ²)	Test method
Ammonium (NH ₄)	0.100	0.060	IENT-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.750	0.520	
Chloride (Cl)	0.600	0.450	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.030	< 0.008	
Nitrate (NO ₃)	0.600	0.450	
Nitrite (NO ₂)	0.050	< 0.008	
Phosphate (PO ₄)	0.050	< 0.008	
Potassium (K)	0.050	0.025	
Sodium (Na)	0.080	0.030	
Sulphate (SO ₄)	0.200	0.070	

EXTRA TESTS	Description	Norm
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 - Limulus Amoebocyte Lysate (LAL) kinetic chromogenic test.	EN 455-3:2015
NVR	< 25 µg/cm ² .	IENT-RP-CC005.4
ESD	Tested for electrostatic properties.	EN 1149-1/2/3 & 5
DNase and RNase contamination	DNase and RNase free.	MO BIO Certification

ALLERGIES	
Bio-compatibility	Demonstrated by skin irritation and sensitisation tests in accordance with ISO 10993-10:2021.
Accelerators	Accelerator and sulphur free to minimise 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.
Residual powder	Powder-free to minimise the potential consequences of powder-borne dermatitis. Residual powder content is 1.0 mg/glove (typical) with a limit of 2.0 mg/glove (ISO 21171:2006).
Latex protein	Latex-free.