SHIELDskin™

A REVOLUTION IN GLOVE TECHNOLOGY

ORANGE

BIOLOGICAL RISK

TECHNICAL INFORMATION

SHIELDskin™ ORANGE NITRILE™ 300 Sterile

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

CE 0598

ISO 374-1 Type B JKPT

ISO 374-5:2016 Level 3 VIRUS

⇒ 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 (acrylonitrile butadiene and polychloroprene).
DESIGN	Orange (Outer)/ White (Inner), ambidextrous, beaded cuff, textured fingertips.
PACKAGING	1 pair per PE peel pouch - 20 pouches per sealed poly bag - 8 poly bags per PE bag per carton.

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

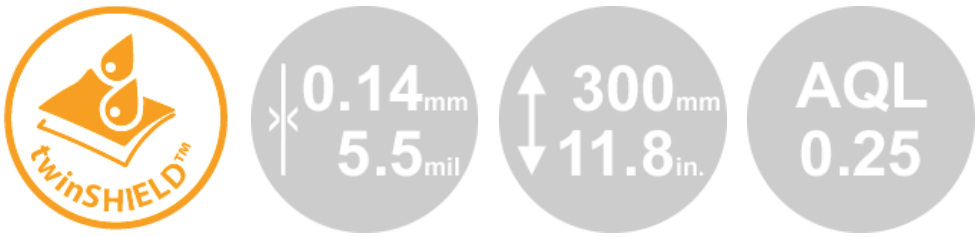
STANDARDS	
CE REGISTRATION	PPE Category III (Complex Design) - Regulation (EU) 2016/425.
EU PPE NORMS	EN 420:2003+A1:2009, EN 421:2010, ISO 374-1:2016+A1:2018, EN 374-2:2014, ISO 374-4:2013, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
EU MDD NORMS[1]	EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009.
USA STANDARDS	ASTM D3767-03 (2014), ASTM D573-04 (2015), ASTM D412-16, ASTM D6978-05 (2019) and IEST-RP-CC005.4 (2013).
OTHER STANDARDS	EN1149-1/2/3 & 5, ISO 21171:2006, ISO 11137-2:2015, ISO 10993-10:2010.

[1] *With reference to Council Directive 93/42/EEC for Medical Devices*

QUALITY	
QUALITY ASSURANCE	Production management in accordance with ISO 9001:2015 and ISO 13485:2016.
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. For an easy access, scan the QR code.
EU TYPE EXAMINATION CERTIFICATE	
PRODUCT INSERT	
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	0.17	6.7	ASTM D3767-03 (2014)
⇒ Palm	0.14	5.5	
⇒ Cuff	0.10	3.9	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 290 mm / 11.4"	300 mm / 11.8"	EN 420:2003+A1:2009

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 (2015) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 Mpa	≥ 400%	8.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 0.25[3] - Level 3	EN 374-2:2014

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

PROTECTION PROPERTIES

RISKS	Description	Norm
MICRO-ORGANISMS	1000 ml water test. Performance level 3, AQL < 0.25 (inspection level G1).	EN 374-2:2014
VIRUSES	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
CHEMICALS	Performance: Type B (JKPT). 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 EN 374-4:2013
RADIOACTIVITY	Protection from radioactive contamination.	EN 421:2010
ESD	Tested for electrostatic properties.	EN 1149-1/2/3 & 5
CLEANLINESS	Compatible with sterile processing. Typical value: < 3.000 particles per cm^2 and at 0.5 µm.	IEST-RP-CC005.4 (2013)
DNase and RNase CONTAMINATION	DNase and RNase free.	MO BIO Certification
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 turbimetric test.	EN 455-3:2015
CYTOTOXIC	Tested for permeation to potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	ASTM D6978-05 (2019)

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.
RESIDUAL POWDER	Powder-free to minimize 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.

SHIELD Scientific
compliance comfort protection

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