SHIELDskin™

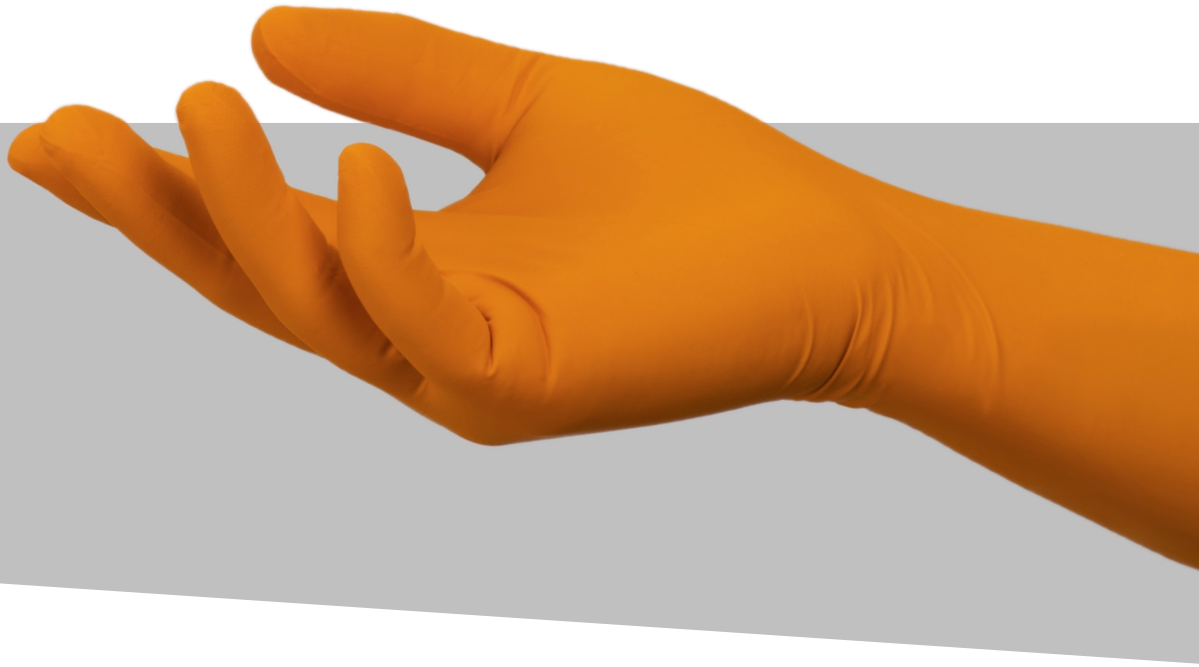
A REVOLUTION IN GLOVE TECHNOLOGY

ORANGE

BIOLOGICAL
RISK

TECHNICAL INFORMATION

SHIELDskin™ ORANGE NITRILE™ 300



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

MDD Medical Device Class I DIRECTIVE 93/42/EEC

CE 0598

ISO 374-1 Type B JKPT

ISO 374-5:2016 Level 3 VIRUS

⇒ Powder-free ambidextrous extra length (300 mm / 11.8") non-sterile nitrile/neoprene protective gloves.

⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.

⇒ Medical Device Class 1 (MDD) according to the Directive 93/42/EEC.

⇒ 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	50 gloves per dispenser - 10 dispensers per carton.

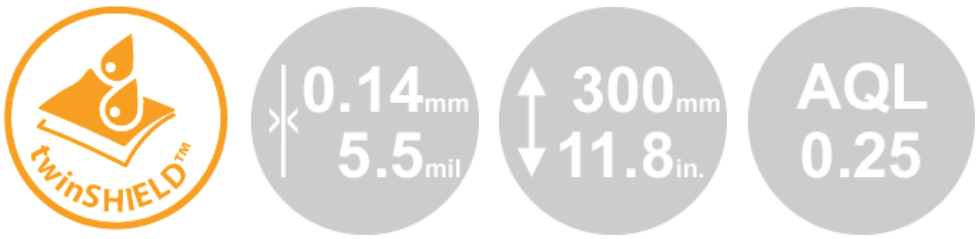
SIZES	6/XS	7/S	8/M	9/L	10/XL	11/XXL
CODES	67 6251	67 6252	67 6253	67 6254	67 6255	67 6256

STANDARDS	
CE REGISTRATION	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND. MDD Class 1 - Directive 93/42/EEC.
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	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).
OTHER STANDARDS	EN1149-1/2/3 & 5, ISO 21171:2006, ISO 10993-10:2010.

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	

PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[1]	mil	Norm
⇒ Finger	0.17	6.7	ASTM D3767-03 (2014)
⇒ Palm	0.14	5.5	
⇒ Cuff	0.10	3.9	

[1] *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[2] - Level 3	EN 374-2:2014 EN 455-1:2000

[2] *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
CYTOTOXIC	Tested for permeation to potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	ASTM D6978-05 (2019)
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.
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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