SHIELDskin™
A REVOLUTION IN GLOVE TECHNOLOGY

ORANGE
BIOLOGICAL RISK

SHIELDskin™
ORANGE NITRILE™ 260

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

MDR Medical Device Class I REGULATION (EU)2017/745

UKCA 0120

CE 0598

ISO 374-1 Type B JKPT

ISO 374-5:2016 Level 3 VIRUS

TECHNICAL INFORMATION

WWW.SHIELDSCIENTIFIC.COM

General Risk ★★★★★

Biological Risk ★★★★★

Chemical Risk ★★★☆☆

⇒ Powder-free ambidextrous extra length (260 mm / 10.2") non-sterile nitrile/neoprene protective gloves.

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

⇒ Medical Device Class 1 (MDR) according to the Regulation (EU) 2017/745.

⇒ 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, ambidextrous, beaded cuff, textured fingertips.
Packaging	90 gloves per dispenser - 10 dispensers per carton = 900 gloves.

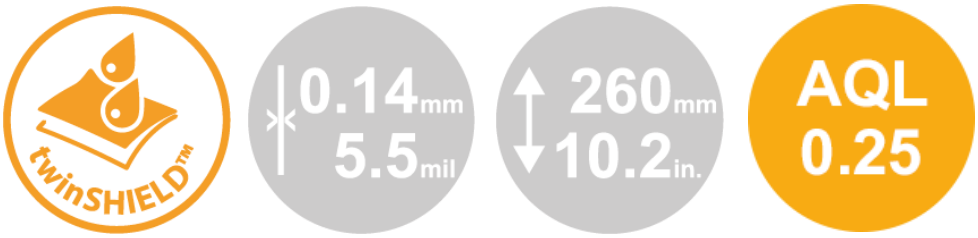
SIZES	6/XS	7/S	8/M	9/L	10/XL
Codes	67 6231	67 6232	67 6233	67 6234	67 6235

STANDARDS	
CE/UKCA registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. CE Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND. UKCA Notified Body No 0120: SGS United Kingdom Ltd, Ellesmere port - UNITED-KINGDOM. MDR Class 1 - Regulation (EU) 2017/745.
EU PPE norms	ISO 21420:2020, 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	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).
Other standards	EN1149-1/2/3 & 5, ISO 21171:2006, 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. For easy access, scan the QR code.
EU type examination certificate	
User's instructions	

PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[1]	mil	Norm
⇒ Finger	0.17	6.7	ASTM D3767-03 (2020)
⇒ 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	≥ 260 mm / 10.2"	265 mm / 10.4"	ISO 21420:2020

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[2] - Level 3	ISO 374-2:2019 EN 455-1:2020

[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).	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 (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 ISO 374-4:2019
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 10993-10:2021.
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

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

File: PDS_F_67623X_EN_SHIELDSKIN_ORANGE-NITRILE-260_EXT_FV_014_30062022_SB.pdf