SMARTLine™

Powder-free blue nitrile gloves, 240

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

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

CE
0598

ISO 374-1
Type C
K

ISO 374-5:2016
Level 2
VIRUS

⇒ Powder-free ambidextrous standard length (240 mm / 9.4") non-sterile nitrile gloves.

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

⇒ 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 synthetic rubber (*acrylonitrile butadiene*).
Design	Blue, ambidextrous, beaded cuff, textured fingers.
Packaging	100 gloves per dispenser (Except 10/XL: 90 gloves per dispenser) - 10 dispensers per carton.

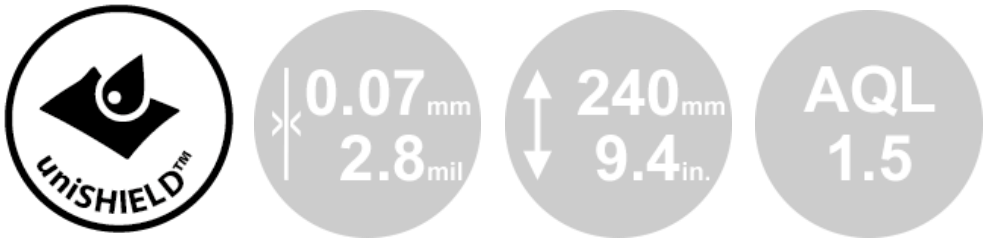
SIZES	6/XS	7/S	8/M	9/L	10/XL
Codes	10 621	10 622	10 623	10 624	10 625

STANDARDS	
CE registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND. MDR Class 1 - Regulation (EU) 2017/745.
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	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.
Other standards	ISO 21171:2006, ISO 10993-10:2010.

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.

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	

PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[1]	mil	Norm
⇒ Finger	0.11	4.3	ASTM D3767-03 (2020)
⇒ Palm	0.07	2.8	
⇒ Cuff	0.05	2.0	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 240 mm / 9.4"	245 mm / 9.6"	ISO 21420:2020 EN 455-2:2015

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 6.0N	14 MPa	≥ 500%	8.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 MPa	≥ 400%	7.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 1.5[2]- Level 2	ISO 374-2:2019 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 2, AQL < 1.5 (inspection level G1).	EN 455-1:2000 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 C (K). Permeation: 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

ALLERGIES	
Bio-compatibility	Demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2010.
Accelerators	Free of Thiazoles and Thiurams. These chemical accelerators are excluded from the manufacturing process.
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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