

SMARTLine™

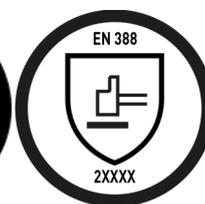
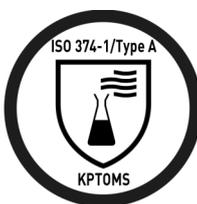
YOUR FIRST LINE OF DEFENCE

VIOLET

GENERAL
SAFETY

SMARTLine™

NEO NITRILE™ 300 DI



TECHNICAL INFORMATION

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DI

Basic
contamination
control

- ⇒ Powder-free single DI washed ambidextrous standard length (300 mm / 11.8") non-sterile neoprene/nitrile 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, viruses and mechanical.

DESCRIPTION	
Formulation	Neoprene and nitrile synthetic rubber (<i>Polychloroprene and acrylonitrile butadiene</i>).
Design	Green, ambidextrous, beaded cuff, textured fingertips.
Packaging	50 gloves per double sealed polybag - 10 double sealed PE bags per tied carton liner - 1 tied carton liner per carton = 500 gloves.

SIZES	6/XS	7/S	8/M	9/L	10/XL	11/XXL
Codes	20 831	20 832	20 833	20 834	20 835	20 836

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+A1:2024, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018, EN 388:2016+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 and IEST-RP-CC005.4 (2013).
Other standards	EN 1149-1/2/3 & 5, ISO 10993-10:2021.

¹With reference to Regulation (EU) 2017/745 for Medical Devices

QUALITY	
Quality assurance	Production management in accordance with EN ISO 9001:2015 and EN ISO 13485:2016. Environmental management systems in accordance with ISO 14001:2015.
Technology	Dual-layer glove: double-walled protection to offer a stronger glove and to reduce risk of pinholes. A green protective outer layer combined with a soft, comfortable violet 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	For easy access, scan the QR code.
User's instructions	
Certificate of conformance	To access CoC, you need to be registered. Please contact us at info@shieldscientific.com or call your SHIELD Scientific representative.



PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm ²	mil	Norm
⇒ Finger	0.28	11.0	ASTM D3767-03 (2020)
⇒ Palm	0.19	7.5	
⇒ Cuff	0.13	5.1	

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"	ISO 21420:2020+A1:2024

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

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 1.0 ³ G1 Level 2	ISO 374-2:2019

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

RISKS	Description	Norm
Micro-organisms	1000 ml water test. Performance level 2, AQL < 1.0 (inspection level G1).	EN 455-1:2020 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 A (KPTOMS). <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

CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm ² ≥ 0.5µm	< 3,000 particles (spec.)	2,100 particles	IEST-RP-CC005.4

EXTRACTABLES (ION)	Specification (µg/cm ²)	Typical value (µg/cm ²)	Test method
Ammonium (NH ₄)	0.100	0.025	IEST-RP-CC005.4
Bromide (Br)	0.050	< 0.008	
Calcium (Ca)	0.750	0.600	
Chloride (Cl)	0.600	0.400	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.030	0.010	
Nitrate (NO ₃)	0.600	0.460	
Nitrite (NO ₂)	0.100	< 0.008	
Phosphate (PO ₄)	0.050	< 0.008	
Potassium (K)	0.050	0.030	
Sodium (Na)	0.080	0.050	
Sulphate (SO ₄)	0.600	0.040	

EXTRA TESTS	Description	Test method
NVR	< 25 µg/cm ² .	IEST-RP-CC005.4
FTIR	Silicone free and non-detectable levels of amide and DOP.	IEST-RP-CC005.4
ESD	Tested for electrostatic properties.	EN 1149-1/2/3 & 5
Mechanical	Level 2 (Abrasion).	EN 388:2016+A1:2018

ALLERGIES	
Bio-Compatibility	Demonstrated by skin irritation and sensitisation tests in accordance with ISO 10993-10:2021.
Accelerators	Free of Thiurams and Thiazoles. These chemicals accelerators are excluded from the manufacturing process.
Latex protein	Latex-free.