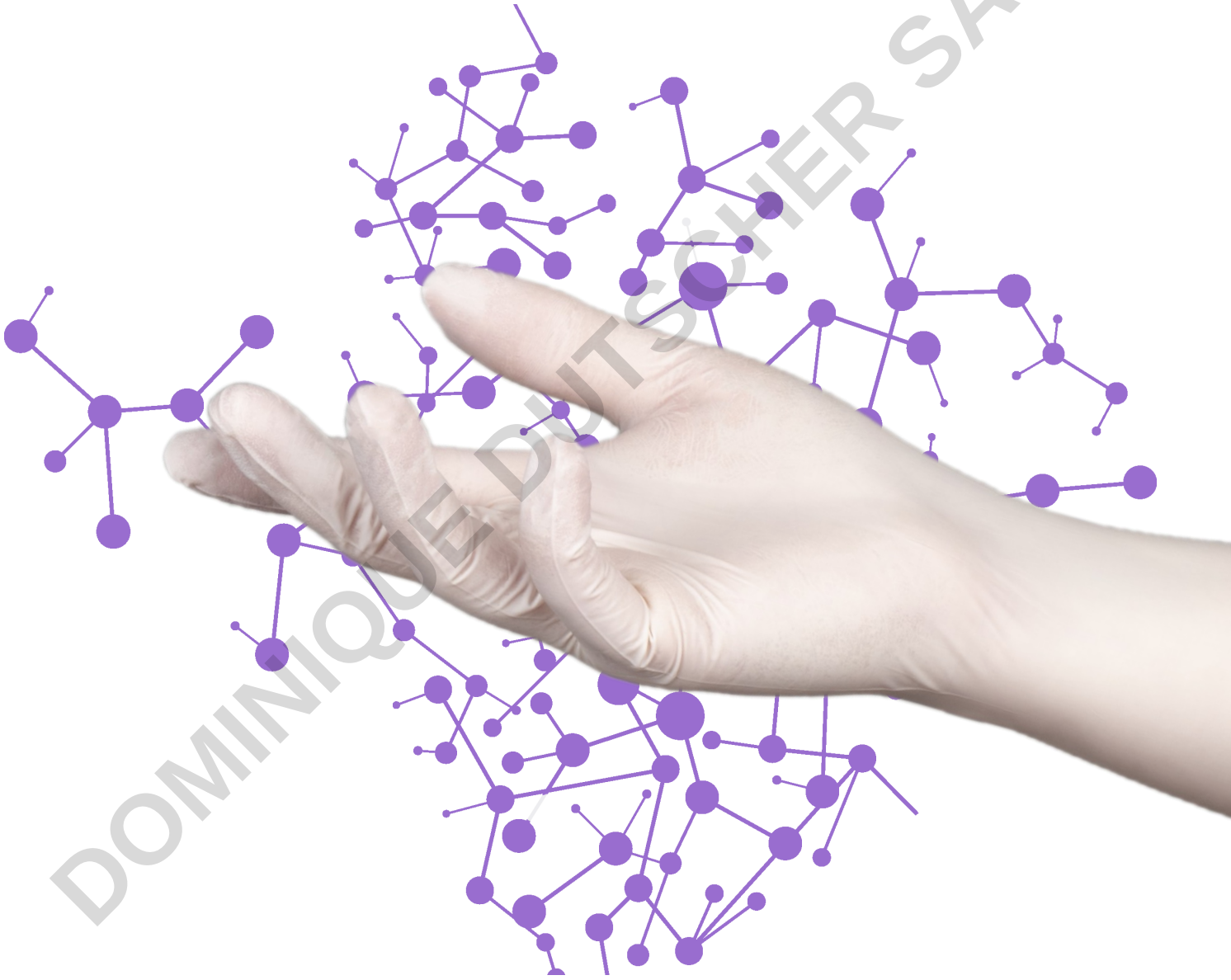
SMARTLine ™

Sterile Light Nitrile 300 DI



DOMINIQUE DUTSCHER SAS

PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425 · CE 2797 · UK CA 0086 · ISO 374-1/Type B KPT · ISO 374-5:2016 VIRUS

Sterile

Bio contamination control

DI

Basic contamination control

⇒ Powder-free single DI washed ambidextrous standard length (300 mm / 11.8") sterile nitrile cleanroom 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 synthetic rubber (*Acrylonitrile butadiene*).
Design	White, ambidextrous, beaded cuff, textured fingertips.
Packaging	1 pair per PE tear pouch - 20 pouches per double sealed PE bag - 10 double sealed PE bags per tied carton liner - 1 tied carton liner per carton = 200 pairs.

SIZES	6/XS	7/S	8/M	9/L	10/XL	11/XXL
Codes	20 631	20 632	20 633	20 634	20 635	20 636

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+A1:2022, 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[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	ISO 11137-2:2015, ISO 10993-10:2021.

[1] *With 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	uniSHIELD™ single-walled protection to offer an ideal compromise between comfort and protection. Compatible with sterile processing environments due to paperless packaging and multiple post leaching of gloves (single washed in deionised water).

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	
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	

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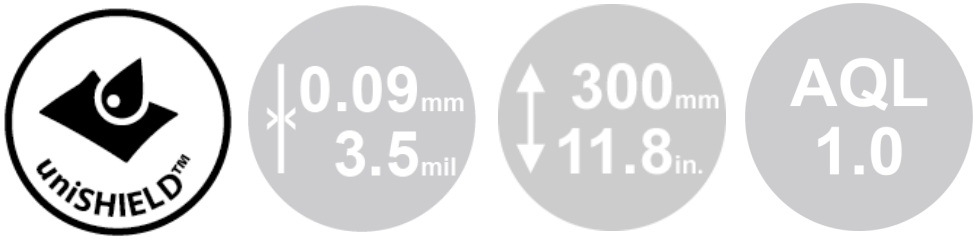
PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[2]	mil	Norm
⇒ Finger	0.12	4.7	ASTM D3767-03 (2020)
⇒ Palm	0.09	3.5	
⇒ Cuff	0.06	2.4	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 290 mm / 11.4"	295 mm / 11.6"	ISO 21420:2020+A1:2022

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).	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 (KPT). 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

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CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm² ≥ 0.5µm	< 3,000 particles (spec.)	2,300 particles	IEST-RP-CC005.4

EXTRACTABLES (ION)	Specification (µg/cm²)	Typical value (µg/cm²)	Test method
Ammonium (NH_4)	0.100	0.075	IEST-RP-CC005.4
Bromide (Br)	0.050	< 0.008	
Calcium (Ca)	0.750	0.600	
Chloride (Cl)	0.600	0.520	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.030	< 0.008	
Nitrate (NO_3)	0.600	0.480	
Nitrite (NO_2)	0.100	< 0.008	
Phosphate (PO_4)	0.050	< 0.008	
Potassium (K)	0.050	0.040	
Sodium (Na)	0.080	0.050	
Sulphate (SO_4)	0.600	0.070	
Zinc (Zn)	1.000	0.520	

EXTRA TESTS	Description	Test method
Sterility	Terminally sterilised by gamma irradiation to Sterility Assurance Level (SAL) of 10^{-6} (ISO 11137-2:2015).	
Endotoxins	Low Endotoxin content at < 20 EU/pair demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic chromogenic test.	EN 455-3:2015
NVR	< 25 µg/cm².	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

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.
Chemical Allergens	Non-detectable levels using aqueous solution extraction (Phosphate buffered solution) and High Performance Liquid Chromatography (HPLC) assay method for quantitative analysis.
Latex protein	Latex-free.

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