

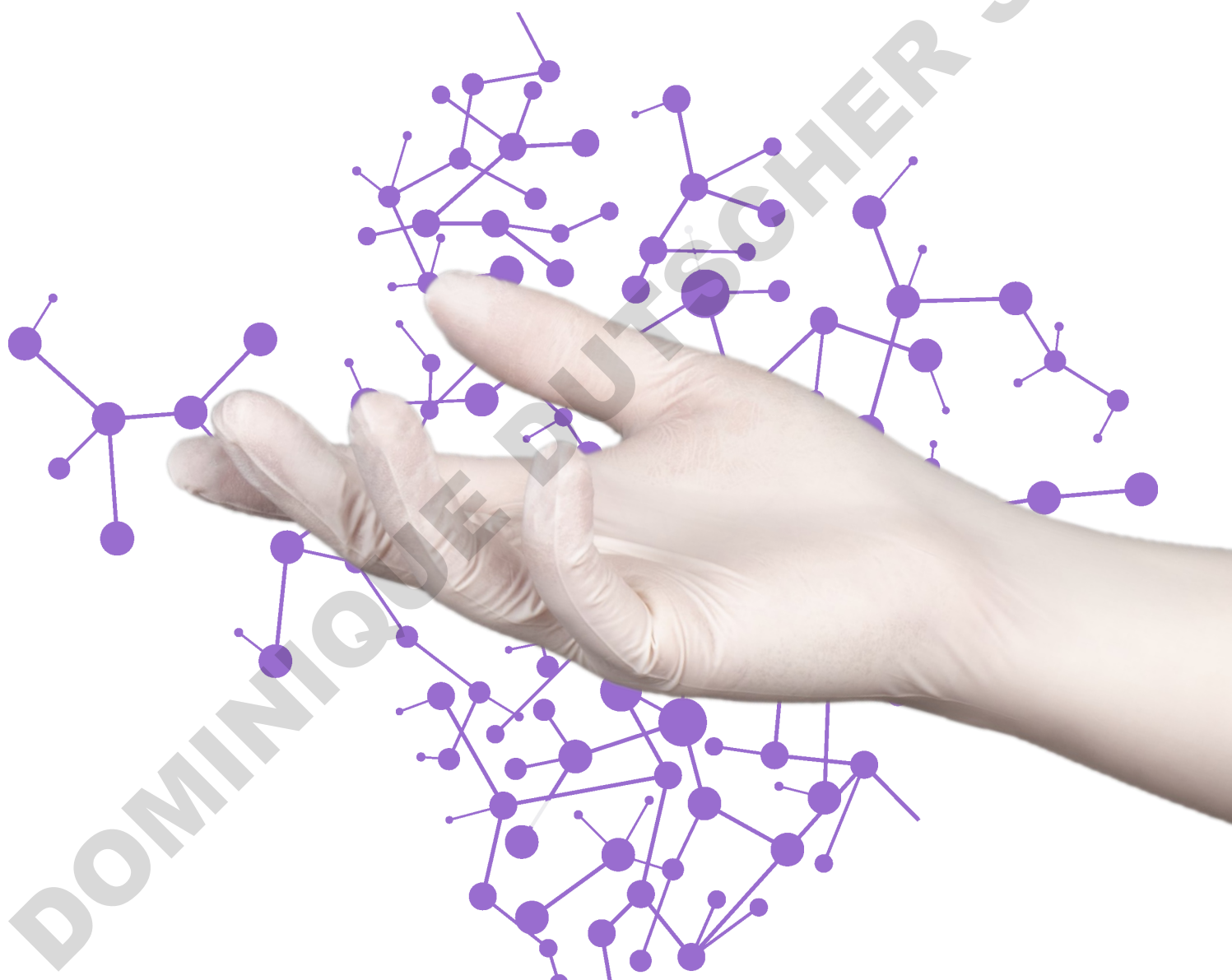
SMARTLine™
YOUR FIRST LINE OF DEFENCE

Sterile

BIO
CONTAMINATION CONTROL

SMARTLine™

Sterile Light Nitrile 300 DI



 **Dutscher**



TECHNICAL INFORMATION

WWW.SHIELDSCIENTIFIC.COM



Sterile

DI

Bio
contamination
control

Basic
contamination
control

- ⇒ Powder-free single DI washed ambidextrous standard length (300 mm / 11.8") sterile nitrile cleanroom gloves.
- ⇒ Personal Protective Equipment Category I (PPE - Simple Design) according to Regulation (EU) 2016/425.
- ⇒ Fully compliant to the latest EU PPE standards.

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 fabricant	20 631	20 632	20 633	20 634	20 635	20 636
Ref. Dutscher	065948	065949	065950	065951	065952	065953

STANDARDS	
CE registration	PPE Category I (Simple Design) - Regulation (EU) 2016/425.
EU PPE norms	ISO 21420:2020+A1:2022, ISO 374-2:2019, 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.

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	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 .
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	

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 G1 ³ - 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
Chemicals	Sodium Hydroxide 40 % Online chemical resistance guide available on www.shieldscientific.com .	EN 16523-1:2015+A1:2018



CLEANLINESS PROPERTIES

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

EXTRACTABLES (ION)	Specification (µg/cm ²)	Typical value (µg/cm ²)	Test method
Ammonium (NH ₄)	0.100	0.075	IENT-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	

EXTRA TESTS	Description	Test method
Sterility	Terminally sterilized 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/cm ² .	IENT-RP-CC005.4
FTIR	Silicone free and non-detectable levels of amide and DOP.	IENT-RP-CC005.4
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	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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