ecoSHIELD™
PROTECT YOUR FUTURE

GREEN
GENERAL RISK

ecoSHIELD™
Eco Latex PF 250

DOMINIQUE DUTSCHER SAS

PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425
MDR Medical Device Class I REGULATION (EU)2017/745
CE 2797
UK CA 0086
ISO 374-1/Type B KPT
ISO 374-5:2016 VIRUS
LATEX

TECHNICAL INFORMATION

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★★★★☆ General Risk

★★☆☆☆ Biological Risk

★★☆☆☆ Chemical Risk

⇒ Powder-free ambidextrous extra length (250-260 mm / 9.8"-10.2") non-sterile natural rubber latex 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	Natural rubber latex (*Hevea brasiliensis*).
Design	Natural colour, ambidextrous, beaded cuff, smooth finish.
Packaging	100 gloves per dispenser - 10 dispensers per carton = 1000 gloves.

SIZES	6/XS	7/S	8/M	9/L	10/XL
Codes	62 3131	62 3132	62 3133	62 3134	62 3135

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. MDR Class 1 - Regulation (EU) 2017/745.
EU PPE norms	ISO 21420:2020+A1:2022, 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 D5712-15.
Other standards	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	uniSHIELD™ single-walled protection to offer an ideal compromise between comfort and protection.
Ecological	Ink on the packaging reduced by 60%. Packaging made from recycled cardboard. Supply chain optimised to reduce CO_2 emissions by more than 15% in the delivery of product.

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	

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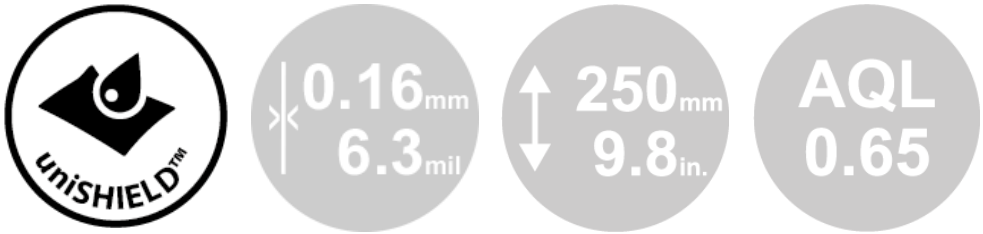
PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[1]	mil	Norm
⇒ Finger	0.19	7.5	ASTM D3767-03 (2020)
⇒ Palm	0.16	6.3	
⇒ Cuff	0.10	3.9	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 250 mm / 9.8"	255 mm / 10.0"	ISO 21420:2020+A1:2022

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 9.0N	18 MPa	≥ 700%	10.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 MPa	≥ 500%	8.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 0.65[2] G1 - Level 3	ISO 374-2:2019 EN 455-1:2020

[2] *AQL as defined per ISO 2859-1:1999 for sampling by attributes.*

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PROTECTION PROPERTIES

RISKS	Description	Norm
Micro-organisms	1000 ml water test. Performance level 3, AQL < 0.65 (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
Radioactivity	Protection from radioactive contamination.	EN 421:2010

ALLERGIES	
Bio-compatibility	Demonstrated by skin irritation and sensitisation tests in accordance with ISO 10993-10:2021.
Accelerators	Free of Thiazoles and Thiurams. These chemical accelerators are excluded from the manufacturing process.
Residual powder	Powder-free to minimise 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	≤ 50 µg/g as per Modified Lowry Method (EN 455-3:2015/ASTM D5712-15).

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