

duoSHIELD™

PFT Latex 240





Dual
risk

- ⇒ Powder-free ambidextrous standard length (240 mm / 9.4") non-sterile natural rubber latex exam 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 (<i>Hevea brasiliensis</i>).
Design	Natural colour, ambidextrous, beaded cuff, fully textured.
Packaging	100 gloves per dispenser - 10 dispensers per carton.

SIZES	6/XS	7/S	8/M	9/L	10/XL
Codes	65 4121	65 4122	65 4123	65 4124	65 4125

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 2017/745.
EU PPE norms	ISO 21420:2020, 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 10993-10:2010.

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.

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	



PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm ¹	mil	Norm
⇒ Finger	0.18	7.1	ASTM D3767-03 (2020)
⇒ Palm	0.14	5.5	
⇒ Cuff	0.12	4.7	

¹ Thickness (+/- 0.03 mm)

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 240 mm / 9.4"	242 mm / 9.5"	ISO 21420:2020 EN 455-2:2015

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 9.0N	18 MPa	≥ 700%	12.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 MPa	≥ 500%	11.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 1.5 ² - Level 2	EN 455-1:2020 ISO 374-2:2019

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 455-1:2020 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 B (KPT). <u>Permeation</u> : 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
Radioactivity	Protection from radioactive contamination.	EN 421:2010
Fit for special purpose	Size and length: Sizes 10 (XL) and 9 (L) gloves are shorter in length than that required by ISO 21420:2020. These gloves are intended for use in light-duty manufacturing and industrial applications where the demand for the advantages of a shorter glove outweighs the need for additional length.	ISO 21420:2020

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	≤ 50 µg/g as per Modified Lowry Method (EN 455-3:2015/ASTM D5712-15). Typical: ≤ 30 µg/g as per Modified Lowry Method.