duoSHIELD PFT Latex 240

pure11-Nr.: 05303, Hersteller: Shield Scientific

Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105303
- Material: Latex
- Beidhändig tragbar
- Puderfrei
- AQL-Wert (Acceptable Quality Level): 1.5
- Voll texturiert
- Reduziertes Allergierisiko (Type I & Type IV)
- Viren- und mikroorganismenresistent

Empfohlene Reinraumklassen

ISO	3	4	5	6	7	8	9
GMP						D	

Produktvarianten

pure11-Nr.: 05303XS
Farbe: Natur / Größe: XS / Herst.-Nr.: 654121 / VE: 1.000 Stück

pure11-Nr.: 05303S
Farbe: Natur / Größe: S / Herst.-Nr.: 654122 / VE: 1.000 Stück

pure11-Nr.: 05303M
Farbe: Natur / Größe: M / Herst.-Nr.: 654123 / VE: 1.000 Stück

pure11-Nr.: 05303L
Farbe: Natur / Größe: L / Herst.-Nr.: 654124 / VE: 1.000 Stück

pure11-Nr.: 05303XL
Farbe: Natur / Größe: XL / Herst.-Nr.: 654125 / VE: 1.000 Stück

pure11 GmbH
Bavariafilmplatz 7 | D-82031 Grünwald
Geschäftsführer: Gitte Hansen, Julian Kropp
AG München HRB 171307

T +49 89 5589434 0
F +49 89 5589434 77
www.pure11.de
info@pure11.de

duoSHIELD™
PFT Latex 240

PPE
Personal Protective Equipment
Category III
REGULATION
(EU) 2016/425

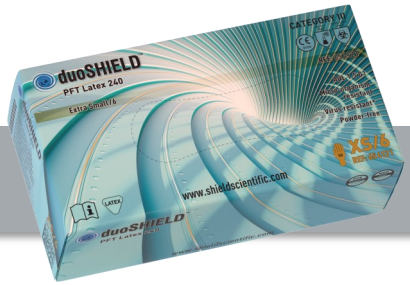
MDR
Medical Device
Class I
REGULATION
(EU)2017/745

CE
0598

ISO 374-1
Type B
KPT

ISO 374-5:2016
Level 2
VIRUS

LATEX



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 (*Hevea brasiliensis*).
Design	Natural colour, ambidextrous, beaded cuff, fully textured.
Packaging	100 gloves per dispenser - 10 dispensers per carton.

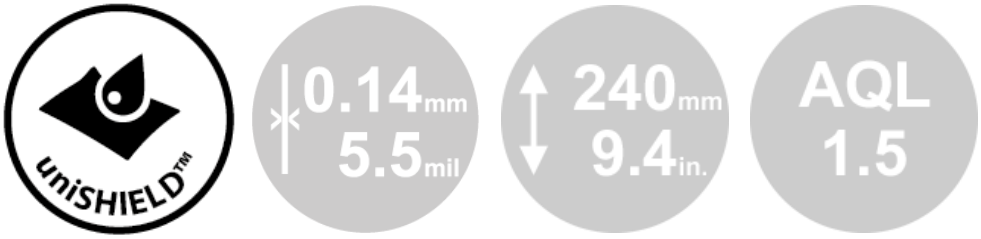
SIZES	6/XS	7/S	8/M	9/L	10/XL
Codes	65 4121	65 4122	65 4123	65 4124	65 4125

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 455-1:2000, 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.
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.
EU type examination certificate	For easy access, scan the QR code.
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 455-1:2000 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 455-1:2000 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: 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
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.

SHIELD Scientific
compliance comfort protection

Dr. Willem Dreeslaan 1 ● 6721 ND Bennekom ● The Netherlands
Phone +31 (0)317 700 202 ● Fax +31 (0)318 503 742
E-mail: Info@shieldscientific.com
www.shieldscientific.com

File: PDS_F_65412X_EN_DUOSHIELD_PFT-Latex-240_EXT_FV_011_15092020_SB.pdf

SHIELD Scientific compliance comfort protection	EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES AND PERSONAL PROTECTIVE EQUIPEMENT		
Originator: J.F ROBLES	**Revision:** 7	**Revision date:** 31.12.2019	**Validity date:** 31.12.2024

PRODUCT	duoSHIELD™ PFT Latex 240
DESCRIPTION	Powder Free Ambidextrous Non-Sterile 24 cm Textured Natural Rubber Gloves
CLASSIFICATION	Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
65 4121	6/XS
65 4122	7/S
65 4123	8/M
65 4124	9/L
65 4125	10/XL

The manufacturer established in the Union:

SHIELD Scientific B.V.

Dr Willem Dreeslaan 1 – 6721 ND BENNEKOM – THE NETHERLANDS

declares under his/her sole responsibility that the Medical Device and PPE (product codes as mentioned above) described hereafter:

duoSHIELD™ PFT Latex 240

is in conformity with the provisions of Council Directive 93/42/EEC and with the national standards transposing harmonized standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009. It is self-certified as a Medical Device Class 1.

is in conformity with the provisions of Regulation (EU) 2016/425 and with the harmonized standards EN ISO 374-1:2016 (as a Type B glove against reagents: K, P & T), EN 374-2:2014 (performance level 2, including protection against viruses), EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016 and EN 420:2003 + A1:2009. This device is identical to the PPE, which is the subject of EU Type Examination (Module B) certificate of conformity *no. FI20/123456 (Technical file submitted/Notified Body answer pending)* issued by the Notified Body:

SGS FIMKO OY (Notified Body No: 0598)
Särkiniementie 3 - 00211 Helsinki - Finland

This device is subject to the procedure set out in Article VIII (Module D) of the Regulation under the surveillance of the Notified Body:

SGS FIMKO OY (Notified Body No: 0598)
Särkiniementie 3 - 00211 Helsinki - Finland

Signed for and behalf of SHIELD Scientific B.V

J.F ROBLES
General Manager

Date: 31th December 2019
Place: Bennekom
Validity of this declaration: 31th December 2019 until 31th December 2024