SHIELDskin Xtreme Bright Latex 300 DI+

pure11-Nr.: 05102, Hersteller: Shield Scientific

Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105102
- Material: Latex
- Farbe: Natur
- Beidhändig tragbar
- Puderfrei
- AQL-Wert (Acceptable Quality Level): 1.5
- Voll texturiert
- Intensiv nachgereinigt
- Virus- & mikroorganismenresistent
- Typischer Partikelwert <900 per cm² = 0.5 µm
- Doppelt unterverpackt

Empfohlene Reinraumklassen

ISO	3	4	**5**	**6**	**7**	**8**	**9**
GMP					**C**	**D**	

Produktvarianten

pure11-Nr.: 05102XS
Größe: XS / Herst.-Nr.: 695651 / VE: 1.000 Stück

pure11-Nr.: 05102S
Größe: S / Herst.-Nr.: 695652 / VE: 1.000 Stück

pure11-Nr.: 05102M
Größe: M / Herst.-Nr.: 695653 / VE: 1.000 Stück

pure11-Nr.: 05102L
Größe: L / Herst.-Nr.: 695654 / VE: 1.000 Stück

pure11-Nr.: 05102XL
Größe: XL / Herst.-Nr.: 695655 / VE: 1.000 Stück

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www.pure11.de
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pure11-Nr.: 05102XXL

Größe: XXL / Herst.-Nr.: 695656 / VE: 1.000 Stück

Quelle: https://www.pure11.de/shieldskin-xtreme-bright-latex-300-di

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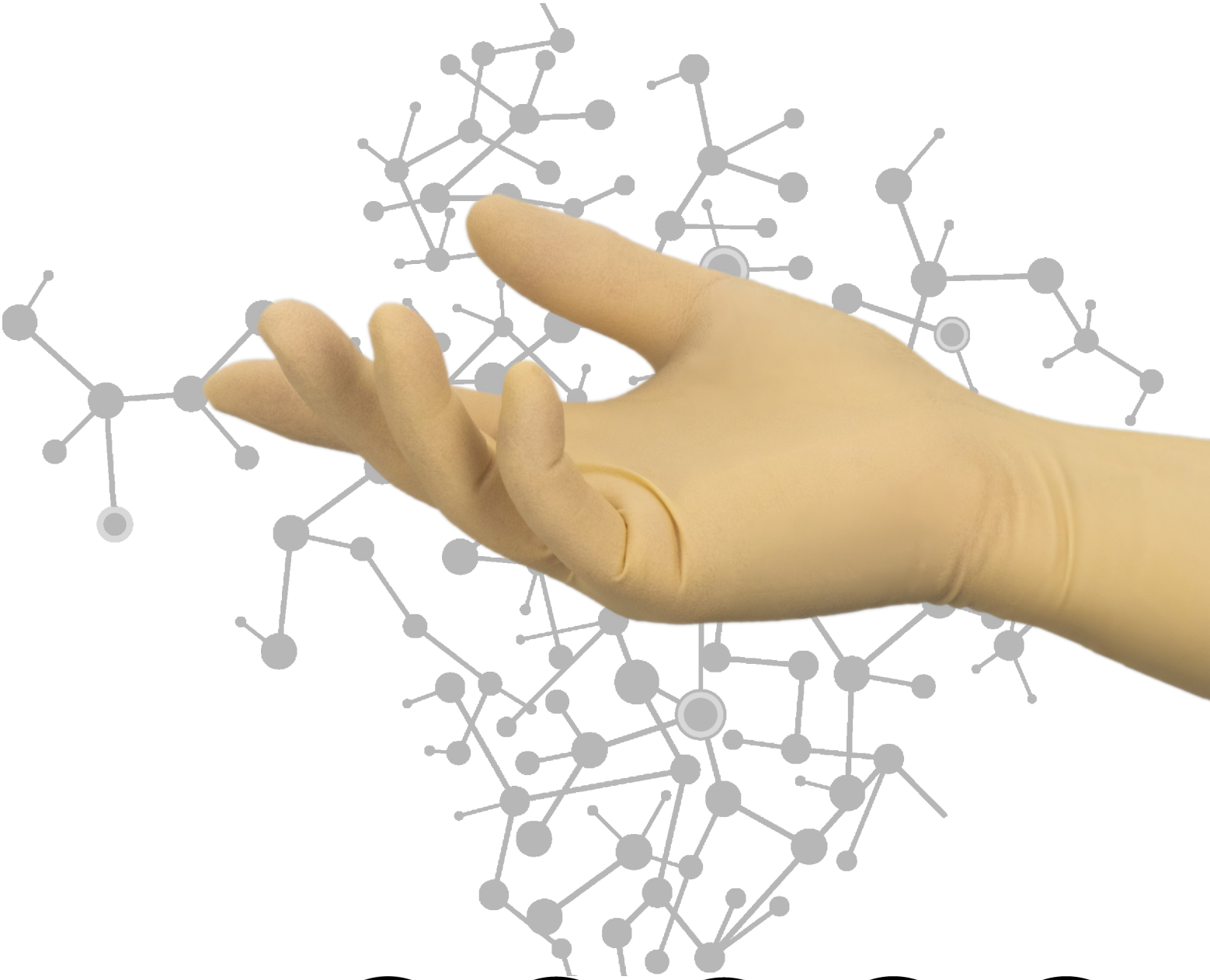
SHIELDskin XTREME™
Bright Latex 300 DI+



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

CE 0598

ISO 374-1 Type B KPT

ISO 374-5:2016 Level 2 VIRUS

LATEX

DI+

High contamination control

⇒ Powder-free triple DI washed ambidextrous standard length (300 mm / 11.8") non-sterile natural rubber latex cleanroom gloves.

⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.

⇒ Fully compliant to the latest PPE Protective gloves EU norms 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 PE bag - 10 bags per polybag - 1 polybag per carton.

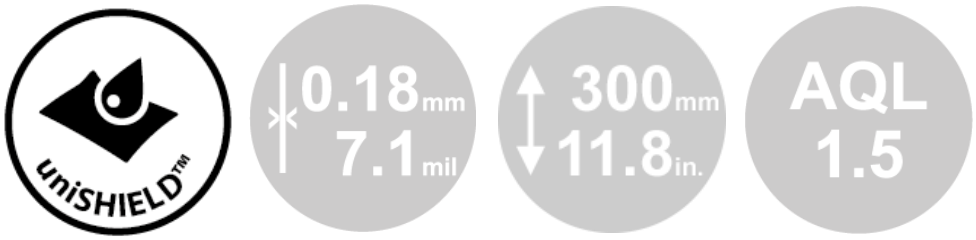
SIZES	6/XS	7/S	8/M	9/L	10/XL	11/XXL
Codes	69 5651	69 5652	69 5653	69 5654	69 5655	69 5656

STANDARDS	
CE registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND.
EU PPE norms	ISO 21420:2020, 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 and IEST-RP-CC005.4 (2013).
Other standards	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. Compatible with clean processing environments due to paperless packaging and multiple post leaching of gloves (triple washed in deionised water).

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	
Certificate of conformance	To access CoC, you need to be registered. Please contact us at info@shieldscientific.com or call your SHIELD Scientific representative.

PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[1]	mil	Norm
⇒ Finger	0.20	7.9	ASTM D3767-03 (2020)
⇒ Palm	0.18	7.1	
⇒ Cuff	0.10	3.9	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 300 mm / 11.8"	305 mm / 12"	ISO 21420:2020

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	ISO 374-2:2019 EN 455-1:2000

[2] *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 < 1.5 (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

CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm² ≥ 0.5µm	< 1,200 particles	1,000 particles	IEST-RP-CC005.4

EXTRACTABLES (ION)	Specification (µg/cm²)	Typical value (µg/cm²)	Test method
Ammonium (NH_4)	0.050	0.015	IEST-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.100	0.080	
Chloride (Cl)	0.750	0.370	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.010	< 0.008	
Nitrate (NO_3)	0.400	0.250	
Nitrite (NO_2)	0.050	< 0.008	
Phosphate (PO_4)	0.050	< 0.008	
Potassium (K)	0.050	0.020	
Sodium (Na)	0.050	0.020	
Sulphate (SO_4)	0.100	0.035	

EXTRA TESTS	Description	Test method
NVR	Maximum 30 µg/g.	IEST-RP-CC005.4
FTIR	Non-detectable levels of silicone, amide and DOP.	IEST-RP-CC005.4

ALLERGIES	
Bio-Compatibility	Demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2010.
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	≤ 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

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File: PDS_F_69565X_EN_SHIELDSKIN-XTREME_Bright-Latex-300-DI-PLUS_EXT_FV_014_15092020_SB.pdf

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CHEMICAL RESISTANCE GUIDE

Level 0	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
<10 min	10 - 30 min	30 - 60 min	60 - 120 min	120 - 240 min	240 - 480 min	> 480 min

SHIELDskin XTREME* Bright Latex 300 DI+

PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425
MDD Medical Device Class I DIRECTIVE 93/42/EEC
CE 0598
ISO 374-1 Type B KPT

- Category III PPE glove (PPE Regulation (EU) 2016/425)
- Complex Design - For mortal & irreversible risks
- Class 1 MDD glove (Council Directive 93/42/EEC)
- Powder-free natural latex glove
- Ambidextrous
- 300 mm / 0.18 mm (EN 420:2003+A1:2009)
- Biological risk (ISO 374-5:2016 VIRUS)
- AQL 1.5 (EN 374-2:2014 Level 2)
- Viral penetration test (ISO 16604:2004 Procedure B)
- Chemical risk (ISO 374-1:2016+A1:2018 - Type B KPT)
- Waterproof and for low chemical protection
- Tested for chemical permeation (EN 16523-1:2015+A1:2018)
- Typical particle levels: less than 1000 per cm² more or equal 0.5µm

67-64-1	Acetone 99,8%	LEVEL 0 1 min
75-05-8	Acetonitrile 99,9%	LEVEL 0 2 min
79-06-1	Acrylamide 40%	LEVEL 6 480 min
1336-21-6	Ammonium Hydroxide 25%	LEVEL 0 9 min
67-68-5	Dimethyl Sulfoxide 99% (DMSO)	LEVEL 3 93 min
64-17-5	Ethanol 99.8%	LEVEL 0 4 min
64-17-5	Ethanol 70%	LEVEL 1 13 min

1239-45-8 Ethidium Bromide 5%	LEVEL 6 480 min
7647-01-0 Hydrochloric Acid 37%	LEVEL 2 44 min
7664-39-3 Hydrofluoric Acid 48%	LEVEL 1 26 min
7664-39-3 Hydrogen Fluoride 48%	LEVEL 1 26 min
7722-84-1 Hydrogen Peroxide 30%	LEVEL 6 480 min
7722-84-1 Hydrogen Peroxide 12%	LEVEL 6 480 min
67-63-0 Isopropanol 100%	LEVEL 0 6 min
67-63-0 Isopropanol 70%	LEVEL 1 14 min
67-56-1 Methanol 99,9%	LEVEL 0 0 min
7697-37-2 Nitric Acid, 50%	LEVEL 1 27 min
1310-73-2 Sodium Hydroxide 40%	LEVEL 5 380 min
7681-52-9 Sodium Hypochlorite 13%	LEVEL 6 480 min
7664-93-9 Sulphuric Acid 50%	LEVEL 6 480 min
1330-20-7 Xylene 98,5%	LEVEL 0 0 min

DISCLAIMER: The data provided was based on gloves tested under laboratory conditions, in accordance with EN 16523-1:2015 (formerly EN 374-3:2003) and EN 374-4:2013. The information is for guidance only and may not reflect the user's application. A risk assessment should always be made by purchaser to assess the suitability of gloves for a specific application.

EU DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES AND PERSONAL PROTECTIVE EQUIPMENT

Originator: J.F ROBLES	**Revision:** 7	**Revision date:** 06.12.2023	**Validity date:** 06.12.2023

PRODUCT	SHIELDskin XTREME™ Bright Latex 300 DI+
DESCRIPTION	Powder Free Extra DI washed Ambidextrous Non-Sterile 30cm Cleanroom Natural Rubber Latex Gloves
CLASSIFICATION	Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	**Sizes**
69 5651	6/XS
69 5652	7/S
69 5653	8/M
69 5654	9/L
69 5655	10/XL
69 5656	11/XXL

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:

SHIELDskin XTREME™ Bright Latex 300 DI+

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. FI18/962483 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: 06th December 2018
Place: Bennekom
Validity of this declaration: 06th December 2018 until 6th December 2023

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Abteilung: Testlabor für Latexproteine
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www.handschuhliste.de

Erlangen, 2009-06-03

Protein determination in natural rubber latex

Date of analysis: 2009-06-02 (mod. Lowry)
Sample: **Powderfree Latex 300mm: SHIELDskin™ Xtreme Bright Latex 300**
Lot: 8K25 1279B
Analysis-No.: 05090403

Extraction: Double glove method with 0.1 M TES pH 7.4 (according to EN 455-3)

Determination : **Modified Lowry (according to EN 455-3):**
Colour development: BioRad *DC* Protein Assay

Results:

	Modified Lowry µg protein / g glove
1. Extraction	<10
2. Extraction	<10
3. Extraction	<10
4. Extraction	<10
Mean	**<10**

Dr. Hans Uwe Koch