



SHIELDskin Xtreme Eco NITRILE 300 DI+

pure¹¹-Nr.: 05006, Hersteller: Shield Scientific

Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105006
- Material: Nitril
- Beidhändig tragbar
- Puderfrei
- Latexfrei
- AQL-Wert (Acceptable Quality Level): 1.5
- Texturierte Fingerspitzen
- Einzigartige Skin Nitrile™ Technologie
- Reduziertes Allergierisiko (Type I & Type IV)
- Mikroorganismenresistent
- Niedrige Partikel- und Ionenrückstandswerte
- 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.: 05006XS

Farbe: Weiß / Größe: XS / Herst.-Nr.: 688651 / VE: 1.500 Stück

pure¹¹-Nr.: 05006S

Farbe: Weiß / Größe: S / Herst.-Nr.: 688652 / VE: 1.500 Stück

pure¹¹-Nr.: 05006M

Farbe: Weiß / Größe: M / Herst.-Nr.: 688653 / VE: 1.500 Stück

pure¹¹-Nr.: 05006L

Farbe: Weiß / Größe: L / Herst.-Nr.: 688654 / VE: 1.500 Stück

pure¹¹-Nr.: 05006XL

Farbe: Weiß / Größe: XL / Herst.-Nr.: 688655 / VE: 1.500 Stück

pure¹¹-Nr.: 05006XXL

Farbe: Weiß / Größe: XXL / Herst.-Nr.: 688656 / VE: 1.500 Stück

Quelle: <https://www.pure11.de/shieldskin-xtreme-eco-nitrile-300-di>

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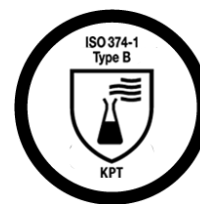
SHIELDskin XTREME™
A REVOLUTION IN GLOVE TECHNOLOGY

DI+

EXTREME
CONTAMINATION CONTROL

SHIELDskin XTREME™

Eco Nitrile 300 DI+





DI+

High contamination control

- ⇒ Powder-free triple DI washed ambidextrous standard length (300 mm / 11.8") non-sterile nitrile 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	Nitrile synthetic rubber (<i>acrylonitrile butadiene</i>).
Design	White, ambidextrous, beaded cuff, textured fingertips.
Packaging	100 gloves per PE bag - 15 bags per polybag - 1 polybag per carton.

SIZES	6/XS	7/S	8/M	9/L	10/XL	11/XXL
Codes	68 8651	68 8652	68 8653	68 8654	68 8655	68 8656

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 and IEST-RP-CC005.4 (2013).
Other standards	EN 1149-1/2/3 & 5, 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. Synthetic soft polymer, based on Skin Nitrile™ technology with a blend of polychloroprene. 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 .
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	0.15	5.9	ASTM D3767-03 (2020)
⇒ Palm	0.10	3.9	
⇒ Cuff	0.07	2.8	

¹ Thickness (+/- 0.03 mm)

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 285 mm / 11.2"	300 mm / 11.8"	ISO 21420:2020

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 6.0N	14 MPa	≥ 500%	10.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 MPa	≥ 400%	8.0N	

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	<u>Performance</u> : Type B (KPT). <u>Permeation</u> : Extensively tested. 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

CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm ² ≥ 0.5µm	< 1,200 particles	1,100 particles	IEST-RP-CC005.4

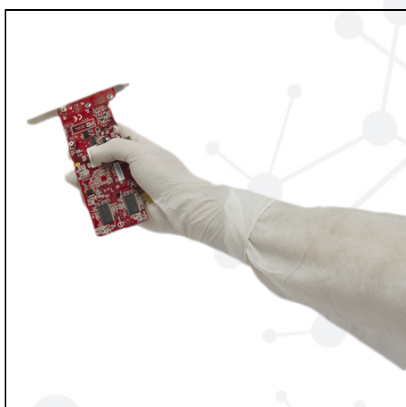
EXTRACTABLES (ION)	Specification (µg/cm ²)	Typical value (µg/cm ²)	Test method
Ammonium (NH ₄)	0.050	0.015	IEST-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.300	0.190	
Chloride (Cl)	0.200	0.110	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.010	< 0.008	
Nitrate (NO ₃)	0.200	0.100	
Nitrite (NO ₂)	0.050	< 0.008	
Phosphate (PO ₄)	0.050	< 0.008	
Potassium (K)	0.050	0.020	
Sodium (Na)	0.050	0.010	
Sulphate (SO ₄)	0.050	0.010	
Zinc (Zn)	0.050	0.030	

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
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 10993-10:2010.
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	Latex-free.



SHIELDskin XTREME* Eco Nitrile 300 DI+



- 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 white nitrile glove
- Ambidextrous
- 300 mm / 0.10 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 1100 per cm² more or equal 0.5µm

67-64-1 Acetone 99,8%	LEVEL 0 0 min
75-05-8 Acetonitrile 99,9%	LEVEL 0 0 min
79-06-1 Acrylamide 40%	LEVEL 6 480 min
1336-21-6 Ammonium Hydroxide 25%	LEVEL 1 16 min
67-66-3 Chloroform 99,8%	LEVEL 0 0 min
109-89-7 Diethylamine 99,5%	LEVEL 0 0 min
68-12-2 Dimethyl Formamide 99,8%	LEVEL 0 1 min

67-68-5 Dimethyl Sulfoxide 99% (DMSO)	LEVEL 0 9 min
64-17-5 Ethanol 99.8%	LEVEL 1 11 min
64-17-5 Ethanol 70%	LEVEL 1 22 min
1239-45-8 Ethidium Bromide 5%	LEVEL 6 480 min
141-78-6 Ethyl Acetate 99.8%	LEVEL 0 0 min
50-00-0 Formaldehyde 37%	LEVEL 6 480 min
7647-01-0 Hydrochloric Acid 37%	LEVEL 3 74 min
7647-01-0 Hydrochloric Acid conc.	LEVEL 3 79 min
7664-39-3 Hydrofluoric Acid 40%	LEVEL 0 8 min
7722-84-1 Hydrogen Peroxide 30%	LEVEL 6 480 min
67-63-0 Isopropanol 100%	LEVEL 2 35 min
67-63-0 Isopropanol 70%	LEVEL 2 45 min
67-56-1 Methanol 99,9%	LEVEL 0 0 min
142-82-5 n-Heptane 99%	LEVEL 2 41 min

7697-37-2 Nitric acid 65%	LEVEL 0 5 min
108-95-2 Phenol 0.1% solution	LEVEL 6 480 min
1310-58-3 Potassium Hydroxide 40%	LEVEL 6 480 min
1310-73-2 Sodium Hydroxide, 50%	LEVEL 6 480 min
7664-93-9 Sulphuric Acid 50%	LEVEL 6 480 min
75-59-2 Tetramethylammonium hydroxide 2.5%	LEVEL 6 480 min
1330-20-7 Xylene 98,5%	LEVEL 0 2 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: 8

Revision date: 18.06.2018

Validity date: 18.06.2023

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

SHIELD Scientific codes	Sizes
68 8651	6/XS
68 8652	7/S
68 8653	8/M
68 8654	9/L
68 8655	10/XL
68 8656	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™ Eco Nitrile 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. F118/961632 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: 18th June 2018

Place: Bennekom

Validity of this declaration: 18th June 2018 until 18th June 2023



ESD CERTIFICATE

Product Description: **SHIELDskin Xtreme™ eco NITRILE 300 DI+**
White Nitrile gloves, non sterile

Certificate Number: 1669/12 and T1210132

Date: 02.08. 2012

Test with 3 pairs/6 pieces in accordance with
EN1149-1:2006 Protective Clothing - Electrostatic properties
- Part 1: Test method for measurement of surface resistivity
(Certificate 1669/12) samples tested as received

Surface Resistivity Information in accordance with EN1149-2:2006		
	Maximum Ohms in accordance to EN1149-5	Measured Ohms
	$2,5 \times 10^9 \Omega$	$7,10 \times 10^{11} \Omega$

Air temperature = 23°C ± 1

Relative humidity = 25 % ± 2 %

Test with 3 pairs/6 pieces in accordance with
EN1149-2:1998 Protective Clothing - Electrostatic properties
- Part 2: Test method for measurement of vertical resistance
(Certificate 1669/12) samples tested as received

Vertical Resistance Information in accordance with EN1149-2:1998		
Maximum Ohms In accordance to EN1149-5	Maximum Value in accordance with TRGS 2153 (Technische Regeln für Gefahrstoffe) BG Germany	Measured Ohms
Not applicable	$< 10^8 \Omega$	$7,15 \times 10^7 \Omega$

Air temperature = 23°C ± 1

Relative humidity = 25 % ± 2 %

Test laboratory/Notified Body: Eurotextil d.o.o., 10000 Zagreb, Croatia

EN 1149-5:2008 Protective clothing - Electrostatic Properties
- Part 5: Material performance and design requirements

The data provided is based on gloves tested under laboratory conditions, in accordance with EN1149-1:2006, EN1149-2:1998, EN1149-3:2004 and EN1149-5:2008. 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. There is no test standard for in-use resistivity which is part of EN1149-5 for gloves.

Test with 3 pcs in accordance with
EN1149-3:2004 Protective Clothing - Electrostatic properties

- Part 3: Test method for induction decay
(Certificate T1210132) samples tested as received
Dimension of the specimens: samples too small, measurement made with little ring

Induction Decay Information in accordance with EN1149-3:2004		
Shielding Factor S	Electrostatic dissipative if	Measured Half decay time T50 (S)
0,00	T50 <4 S	5,26

Air temperature = 23°C

Relative humidity = 25 %

Test laboratory/Notified Body: Centexbel-Verviers, 4650 Herve, Belgium

In accordance with EN 1149-5:2008 Protective clothing - Electrostatic Properties

- Part 5: Material performance and design requirements

SHIELD Scientific B.V.



Cisco ROBLES
General Manager

The data provided is based on gloves tested under laboratory conditions, in accordance with EN1149-1:2006, EN1149-2:1998, EN1149-3:2004 and EN1149-5:2008. 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. There is no test standard for in-use resistivity which is part of EN1149-5 for gloves.