



## SHIELDskin Xtreme White Nitrile 400 DI+

pure<sup>11</sup>-Nr.: 05008, Hersteller: Shield Scientific

### Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105008
- Material: Nitril
- Beidhändig tragbar
- Puderfrei
- Latexfrei
- AQL-Wert (Acceptable Quality Level): 1.5
- Texturierte Handinnenfläche und Fingerspitzen
- Einzigartige Skin Nitrile™ Technologie
- Reduziertes Allergierisiko (Type IV)
- Mikroorganismenresistent
- Typischer Partikelwert: <math><950 \text{ per cm}^2 = 0.5\mu\text{m}</math>
- Doppelt unterverpackt

### Empfohlene Reinraumklassen

ISO  3  4  5  6  7  8  9

GMP      C  D

### Produktvarianten

#### pure<sup>11</sup>-Nr.: 05008XS

Farbe: Weiß / Größe: XS / Herst.-Nr.: 698671 / VE: 1.000 Stück

#### pure<sup>11</sup>-Nr.: 05008S

Farbe: Weiß / Größe: S / Herst.-Nr.: 698672 / VE: 1.000 Stück

#### pure<sup>11</sup>-Nr.: 05008M

Farbe: Weiß / Größe: M / Herst.-Nr.: 698673 / VE: 1.000 Stück

#### pure<sup>11</sup>-Nr.: 05008L

Farbe: Weiß / Größe: L / Herst.-Nr.: 698674 / VE: 1.000 Stück

#### pure<sup>11</sup>-Nr.: 05008XL

Farbe: Weiß / Größe: XL / Herst.-Nr.: 698675 / VE: 1.000 Stück

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**pure<sup>11</sup>-Nr.: 05008XXL**

Farbe: Weiß / Größe: XXL / Herst.-Nr.: 698676 / VE: 1.000 Stück

Quelle: <https://www.pure11.de/shieldskin-xtreme-white-nitrile-400-di>

**pure<sup>11</sup> GmbH**

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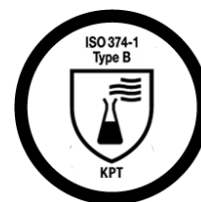
**SHIELDskin XTREME™**  
A REVOLUTION IN GLOVE TECHNOLOGY

**DI+**

HIGH  
CONTAMINATION CONTROL

# SHIELDskin XTREME™

## White Nitrile 400 DI+





DI+

High contamination control

- ⇒ Powder-free triple DI washed ambidextrous extra length (400 mm / 15.7") 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 palm and fingers.
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 8671	69 8672	69 8673	69 8674	69 8675	69 8676

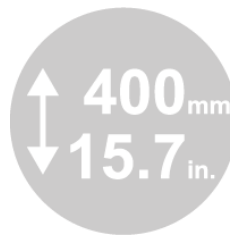
STANDARDS	
CE registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND.
EU PPE norms	ISO 21420:2020, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
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 D6978-05 (2019) 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. 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: <a href="http://www.shieldscientific.com">www.shieldscientific.com</a> .
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 <a href="mailto:info@shieldscientific.com">info@shieldscientific.com</a> or call your SHIELD Scientific representative.



# PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm <sup>1</sup>	mil	Norm
⇒ Finger	0.20	7.9	ASTM D3767-03 (2020)
⇒ Palm	0.15	5.9	
⇒ Cuff	0.10	3.9	

<sup>1</sup> Thickness (+/- 0.03 mm)

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 385 mm / 15.2"	400 mm / 15.7"	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 <sup>2</sup> - Level 2	ISO 374-2:2019 EN 455-1:2000

<sup>2</sup> 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 <sup>3</sup>	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
Chemicals <sup>3</sup>	<u>Performance</u> : Type B (KPT). <u>Permeation</u> : Extensively tested. Online chemical resistance guide on <a href="http://www.shieldscientific.com">www.shieldscientific.com</a> . <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
Cytotoxic	Tested for permeation by potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	ASTM D6978-05 (2019)

<sup>3</sup> For PPE compliance, > 40 cm gloves are palm and cuff tested for permeation, degradation and viral penetration.

# CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm <sup>2</sup> ≥ 0.5µm	< 1,200 particles	1,000 particles	IEST-RP-CC005.4

EXTRACTABLES (ION)	Specification (µg/cm <sup>2</sup> )	Typical value (µg/cm <sup>2</sup> )	Test method
Ammonium (NH <sub>4</sub> )	0.050	0.017	IEST-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.200	0.160	
Chloride (Cl)	0.200	0.110	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.010	< 0.008	
Nitrate (NO <sub>3</sub> )	0.200	0.130	
Nitrite (NO <sub>2</sub> )	0.050	< 0.008	
Phosphate (PO <sub>4</sub> )	0.050	< 0.008	
Potassium (K)	0.050	0.020	
Sodium (Na)	0.050	0.020	
Sulphate (SO <sub>4</sub> )	0.050	0.020	

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\* White Nitrile 400 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
- 400 mm / 0.15 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 cm<sup>2</sup> more or equal 0.5µm

108-24-7 Acetic anhydride	LEVEL 0 6 min
79-06-1 Acrylamide 40%	LEVEL 6 480 min
1336-21-6 Ammonium Hydroxide 25%	LEVEL 2 32 min
1336-21-6 Ammonium hydroxide, 28-30%	LEVEL 1 29 min
64-17-5 Ethanol 99.8%	LEVEL 1 22 min
64-17-5 Ethanol 70%	LEVEL 2 52 min
1239-45-8 Ethidium Bromide 5%	LEVEL 6 480 min

50-00-0 Formaldehyde 37%	LEVEL 6 480 min
7647-01-0 Hydrochloric Acid 37%	LEVEL 4 157 min
7664-39-3 Hydrofluoric Acid 40%	LEVEL 1 15 min
7722-84-1 Hydrogen Peroxide 30%	LEVEL 6 480 min
67-63-0 Isopropanol 100%	LEVEL 3 72 min
67-63-0 Isopropanol 70%	LEVEL 3 95 min
1310-58-3 Potassium Hydroxide 40%	LEVEL 6 480 min
110-86-1 Pyridine	LEVEL 0 3 min
143-33-9 Sodium cyanide	LEVEL 6 480 min
1310-73-2 Sodium Hydroxide 40%	LEVEL 6 480 min
7681-52-9 Sodium Hypochlorite 13%	LEVEL 6 480 min
7664-93-9 Sulphuric Acid 50%	LEVEL 6 480 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.





**SHIELD Scientific**  
compliance comfort protection

## EU DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES AND PERSONAL PROTECTIVE EQUIPEMENT

Originator: J.F ROBLES

Revision: 6

Revision date: 31.12.2019

Validity date: 31.12.2024

<b>PRODUCT</b>	SHIELDskin XTREME™ White Nitrile 400 DI+
<b>DESCRIPTION</b>	Powder Free Extra DI washed Ambidextrous Non-Sterile 40cm Cleanroom Nitrile Gloves
<b>CLASSIFICATION</b>	Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
69 8671	6/XS
69 8672	7/S
69 8673	8/M
69 8674	9/L
69 8675	10/XL
69 8676	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™ White Nitrile 400 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. F120/123456 (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: 31<sup>th</sup> December 2019

Place: Bennekom

Validity of this declaration: 31<sup>th</sup> December 2019 until 31<sup>th</sup> December 2024