



## SHIELDskin Xtreme Sterile White Nitrile 600 DI+

pure<sup>11</sup>-Nr.: 05208, Hersteller: Shield Scientific



### Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105208
- Material: Nitril
- Handspezifisch
- Puderfrei
- Latexfrei
- AQL-Wert (Acceptable Quality Level): 0.65
- Gammasterilisiert
- Texturierte Handinnenfläche und Fingerspitzen
- Reduziertes Allergierisiko (Type I & Type IV)
- Mikroorganismenresistent
- Typischer Partikelwert <math><950 \text{ per cm}^2 = 0.5 \mu\text{m}</math>

### Empfohlene Reinraumklassen

ISO  3  4  5  6  7  8  9

GMP    A/B   C  D

### Produktvarianten

**pure<sup>11</sup>-Nr.: 052086**

Farbe: Weiß / Größe: 6,0 / Herst.-Nr.: 698782 / VE: 100 Paar

**pure<sup>11</sup>-Nr.: 052086b**

Farbe: Weiß / Größe: 6,5 / Herst.-Nr.: 698783 / VE: 100 Paar

**pure<sup>11</sup>-Nr.: 052087**

Farbe: Weiß / Größe: 7,0 / Herst.-Nr.: 698784 / VE: 100 Paar

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**pure<sup>11</sup>-Nr.: 052087b**

Farbe: Weiß / Größe: 7,5 / Herst.-Nr.: 698785 / VE: 100 Paar

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**pure<sup>11</sup>-Nr.: 052088**

Farbe: Weiß / Größe: 8,0 / Herst.-Nr.: 698786 / VE: 100 Paar

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**pure<sup>11</sup>-Nr.: 052088b**

Farbe: Weiß / Größe: 8,5 / Herst.-Nr.: 698787 / VE: 100 Paar

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**pure<sup>11</sup>-Nr.: 052089**

Farbe: Weiß / Größe: 9,0 / Herst.-Nr.: 698788 / VE: 100 Paar

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**pure<sup>11</sup>-Nr.: 0520810**

Farbe: Weiß / Größe: 10,0 / Herst.-Nr.: 698789 / VE: 100 Paar

Quelle: <https://www.pure11.de/shieldskin-xtreme-sterile-white-nitrile-600-di>



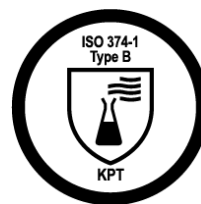
**SHIELDskin XTREME™**  
A REVOLUTION IN GLOVE TECHNOLOGY

**Sterile**

BIO  
CONTAMINATION CONTROL

# SHIELDskin XTREME™

## Sterile White Nitrile 600 DI+





Sterile

DI+

Bio contamination control

High contamination control

- ⇒ Powder-free triple DI washed hand-specific extra length (600 mm / 23.6") sterile nitrile cleanroom gloves.
- ⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.
- ⇒ Fully compliant to the latest EU PPE norms relating to protective gloves against chemicals, micro-organisms and viruses.

DESCRIPTION	
Formulation	Synthetic soft nitrile polymer ( <i>Acrylonitrile Butadiene</i> ).
Design	White, hand-specific, beaded cuff, textured palm and fingers.
Packaging	1 pair per PE peel pouch - 20 pouches per sealed poly bag - 5 poly bags per PE bag per carton.

SIZES	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9	10
Codes	69 8781	69 8782	69 8783	69 8784	69 8785	69 8786	69 8787	69 8788	69 8789

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 <sup>1</sup>	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	ISO 11137-2:2015, ISO 10993-10:2010.

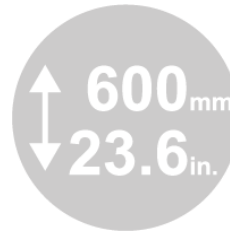
<sup>1</sup>With reference to Regulation (EU) 2017/425 for Medical Devices

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 sterile 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 and CoI, 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.
Certificate of irradiation	



# PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm <sup>2</sup>	mil	Norm
⇒ Finger	0.20	7.9	ASTM D3767-03 (2020)
⇒ Palm	0.17	6.7	
⇒ Cuff	0.11	4.3	

<sup>2</sup> Thickness (+/- 0.03 mm)

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 580 mm / 22.8"	600 mm / 23.6"	ISO 21420:2020

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
	⇒ Before aging	≥ 6.0N	14 MPa	≥ 500%	
⇒ After aging	≥ 6.0N	14 MPa	≥ 400%	9.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 0.65 <sup>3</sup> - Level 3	ISO 374-2:2019

<sup>3</sup> AQL as defined per ISO 2859-1:1999 for sampling by attributes.

RISKS	Description	Norm
Micro-organisms	1000 ml water test. Performance level 3, AQL < 0.65 (inspection level G1).	ISO 374-2:2019
Viruses <sup>4</sup>	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
Chemicals <sup>4</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

<sup>4</sup> For PPER 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	0.015	IEST-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.350	0.200	
Chloride (Cl)	0.200	0.090	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.010	< 0.008	
Nitrate (NO <sub>3</sub> )	0.030	0.020	
Nitrite (NO <sub>2</sub> )	0.030	< 0.008	
Phosphate (PO <sub>4</sub> )	0.030	< 0.008	
Potassium (K)	0.050	0.020	
Sodium (Na)	0.050	0.011	
Sulphate (SO <sub>4</sub> )	0.050	0.008	

EXTRA TESTS	Description	Test method
Sterility	Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10 <sup>-6</sup> (ISO 11137-2:2015).	
Endotoxins	Low Endotoxin content at < 20 EU/pair demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test.	EN 455-3:2015
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 Thiazoles and Thiurams. These chemical 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.

# CHEMICAL RESISTANCE GUIDE



## SHIELDskin XTREME\* Sterile White Nitrile 600 DI+



- Category III PPE glove (PPE Regulation (EU) 2016:425)
- Complex Design - For mortal & irreversible risks
- Powder-free white nitrile glove
- Hand-specific
- 600 mm / 0.17 mm (EN 420:2003+A1:2009)
- Biological risk (ISO 374-5:2016 VIRUS)
- AQL 0.65 (EN 374-2:2014 Level 3)
- 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 supersedes EN 374-3:2003)
- Typical particle levels: less than 1000 per cm<sup>2</sup> more or equal 0.5µm
- Tested according to EN 1149-1-2-3 & 5

50-00-0 Formaldehyde 37%	<b>LEVEL 6</b> 480 min DR 27%
7722-84-1 Hydrogen Peroxide 30%	<b>LEVEL 3</b> 91 min
67-63-0 Isopropanol 70%	<b>LEVEL 4</b> 162 min
1310-73-2 Sodium Hydroxide 40%	<b>LEVEL 6</b> 480 min DR -7%
7681-52-9 Sodium Hypochlorite 13%	<b>LEVEL 6</b> 480 min
75-59-2 Tetramethylammonium hydroxide 2.5%	<b>LEVEL 6</b> 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.







# EU DECLARATION OF CONFORMITY

FOR PERSONAL PROTECTIVE EQUIPEMENT

Originator: J.F ROBLES

Revision: 6

Revision date: 31.12.2019

Validity date: 31.12.2024

<b>PRODUCT</b>	SHIELDskin XTREME™ Sterile White Nitrile 600 DI+
<b>DESCRIPTION</b>	Powder Free Extra DI washed Pair-packed Hand-specific 60cm Cleanroom Gloves
<b>CLASSIFICATION</b>	Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
69 8781	5.5
69 8782	6
69 8783	6.5
69 8784	7
69 8785	7.5
69 8786	8
69 8787	8.5
69 8788	9
69 8789	10

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 PPE (product codes as mentioned above) described hereafter:

### SHIELDskin XTREME™ Sterile White Nitrile 600 DI+

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 3, 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: 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