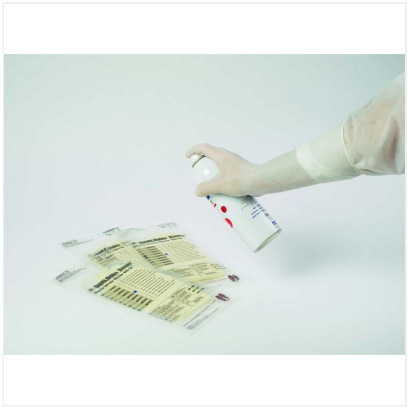

SHIELDskin Xtreme Sterile White Nitrile 400 DI+

pure[11]-Nr.: 05205, Hersteller: Shield Scientific

STERIL

Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105205
- 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 <950 per cm² = 0.5 µm

Empfohlene Reinraumklassen

ISO	3	4	5	6	7	8	9
GMP			A/B		C	D	

Produktvarianten

pure[11]-Nr.: 052056
Farbe: Weiß / Größe: 6,0 / Herst.-Nr.: 698772 / VE: 160 Paar

pure[11]-Nr.: 052056b
Farbe: Weiß / Größe: 6,5 / Herst.-Nr.: 698773 / VE: 160 Paar

pure[11]-Nr.: 052057
Farbe: Weiß / Größe: 7,0 / Herst.-Nr.: 698774 / VE: 160 Paar

pure[11] GmbH
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Geschäftsführer: Gitte Hansen, Julian Kropp
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pure11-Nr.: 052057b
Farbe: Weiß / Größe: 7,5 / Herst.-Nr.: 698775 / VE: 160 Paar

pure11-Nr.: 052058
Farbe: Weiß / Größe: 8,0 / Herst.-Nr.: 698776 / VE: 160 Paar

pure11-Nr.: 052058b
Farbe: Weiß / Größe: 8,5 / Herst.-Nr.: 698777 / VE: 160 Paar

pure11-Nr.: 052059
Farbe: Weiß / Größe: 9,0 / Herst.-Nr.: 698778 / VE: 160 Paar

pure11-Nr.: 0520510
Farbe: Weiß / Größe: 10,0 / Herst.-Nr.: 698779 / VE: 160 Paar

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SHIELDskin XTREME™
A REVOLUTION IN GLOVE TECHNOLOGY

Sterile
BIO
CONTAMINATION CONTROL

SHIELDskin XTREME™
Sterile White Nitrile 400 DI+

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

CE
0598

ISO 374-1
Type B
KPT

ISO 374-5:2016
Level 3
VIRUS

Sterile

Bio contamination control

DI+

High contamination control

⇒ Powder-free triple DI washed hand-specific extra length (400 mm / 15.7") 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 (*acrylonitrile butadiene*).
Design	White, hand-specific, beaded cuff, textured palm and fingers.
Packaging	1 pair per PE peel pouch - 20 pouches per sealed poly bag - 8 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 8771	69 8772	69 8773	69 8774	69 8775	69 8776	69 8777	69 8778	69 8779

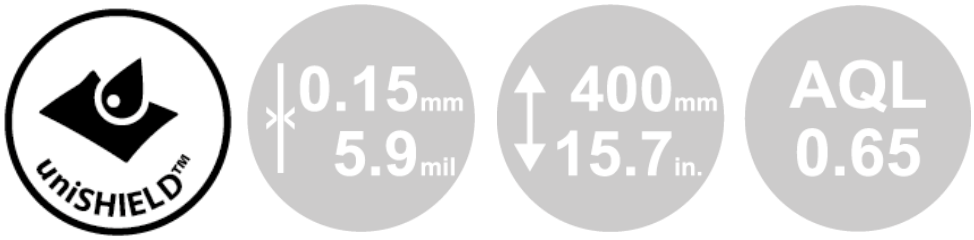
STANDARDS	
CE registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND.
EU PPE norms	ISO 21420:2020, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
EU MDR norms[1]	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	ISO 11137-2:2015, ISO 10993-10:2010.

[1] *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.Synthetic soft polymer based on Skin Nitrile™ technology. 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: www.shieldscientific.com.
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 info@shieldscientific.com or call your SHIELD Scientific representative.
Certificate of irradiation	

PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[2]	mil	Norm
⇒ Finger	0.18	7.1	ASTM D3767-03 (2020)
⇒ Palm	0.15	5.9	
⇒ Cuff	0.10	3.9	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 400 mm / 15.7"	405 mm / 15.9"	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)	< 0.65[3] - Level 3	ISO 374-2:2019 EN 455-1:2000

[3] *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[4]	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
Chemicals[4]	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
Cytotoxic	Tested for permeation to potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	ASTM D6978-05 (2019)

[4] *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/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	0.018	IEST-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.350	0.250	
Chloride (Cl)	0.200	0.110	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.010	< 0.008	
Nitrate (NO_3)	0.200	0.050	
Nitrite (NO_2)	0.050	< 0.008	
Phosphate (PO_4)	0.050	< 0.008	
Potassium (K)	0.050	0.023	
Sodium (Na)	0.050	0.012	
Sulphate (SO_4)	0.050	0.015	

EXTRA TESTS	Description	Test method
Sterility	Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10^{-6} (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.

SHIELD Scientific
compliance comfort protection

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www.shieldscientific.com

File: PDS_F_69877X_EN_SHIELDSKIN-XTREME_Sterile-White-Nitrile-400-DI-PLUS_EXT_FV_011_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* Sterile White Nitrile 400 DI+

- Category III PPE glove (PPE Regulation (EU) 2016/425)
- Complex Design - For mortal & irreversible risks
- Powder-free white nitrile glove
- Hand-specific
- 400 mm / 0.15 mm (EN 420:2003+A1:2009)
- AQL 0.65 (EN 374-2:2014 Level 3)
- Biological risk (ISO 374-5:2016 VIRUS)
- Viral penetration test (ISO 16604:2004 Procedure B)
- Chemical risk (ISO 374-1:2016+A1:2018 - Type 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
- Tested according to EN 1149-1-2-3 & 5

64-19-7 Acetic Acid 100%	LEVEL 0 6 min
67-64-1 Acetone 99,8%	LEVEL 0 1 min
75-05-8 Acetonitrile 99,9%	LEVEL 0 1 min
79-06-1 Acrylamide 40%	LEVEL 6 480 min
1336-21-6 Ammonium Hydroxide 25%	LEVEL 1 27 min
110-82-7 Cyclohexane	LEVEL 6 480 min
75-09-2 Dichloromethane 99%	LEVEL 0 0 min

109-89-7 Diethylamine 99,5%	LEVEL 0 0 min
67-68-5 Dimethyl Sulfoxide 99% (DMSO)	LEVEL 2 37 min
64-17-5 Ethanol 99.8%	LEVEL 1 17 min
64-17-5 Ethanol 70%	LEVEL 2 46 min
1239-45-8 Ethidium Bromide 5%	LEVEL 6 480 min
50-00-0 Formaldehyde 37%	LEVEL 6 480 min
111-30-8 Glutaraldehyde 25%	LEVEL 6 480 min
7664-39-3 Hydrofluoric Acid 40%	LEVEL 1 12 min
7722-84-1 Hydrogen Peroxide 30%	LEVEL 6 480 min
67-63-0 Isopropanol 100%	LEVEL 2 43 min
67-63-0 Isopropanol 70%	LEVEL 3 113 min
Mixed Solution Perform sterile concentrate Oxy 2%	LEVEL 6 480 min
Mixed Solution Perform sterile concentrate PAA 3%	LEVEL 6 480 min
Mixed Solution Perform sterile PAA ready to use	LEVEL 6 480 min

1310-73-2 Sodium Hydroxide 40%	LEVEL 6 480 min
7681-52-9 Sodium Hypochlorite 13%	LEVEL 6 480 min
Mixed Solution SPOR-KLENZ Solution	LEVEL 6 480 min
7664-93-9 Sulphuric Acid 95%-98%	LEVEL 0 7 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 PERSONAL PROTECTIVE EQUIPEMENT		
Originator: J.F ROBLES	**Revision:** 8	**Revision date:** 31.12.2019	**Validity date:** 31.12.2024

PRODUCT	SHIELDskin XTREME™ Sterile White Nitrile 400 DI+
DESCRIPTION	Powder Free Extra DI washed Pair-packed Hand-specific 40cm Cleanroom Gloves
CLASSIFICATION	Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
69 877	5.5
69 8772	6
69 8773	6.5
69 8774	7
69 8775	7.5
69 8776	8
69 8777	8.5
69 8778	9
69 8779	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 400 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

SHIELD Scientific compliance comfort protection

J.F ROBLES
General Manager

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