SHIELDskin Xtreme Sterile White Nitrile 330 DI+

pure[11]-Nr.: 05203, Hersteller: Shield Scientific

STERIL ZYTO

Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105203
- 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 <1200 per cm² = 0.5 µm
- Gut geeignet zum Double-Gloving
- Beständig gegen eine Vielzahl von Zytostatika

Empfohlene Reinraumklassen

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

Produktvarianten

pure[11]-Nr.: 052035b
Farbe: Weiß / Größe: 5,5 / Herst.-Nr.: 698761 / VE: 200 Paar

pure[11]-Nr.: 052036
Farbe: Weiß / Größe: 6,0 / Herst.-Nr.: 698762 / VE: 200 Paar

pure[11] GmbH
Bavariafilmplatz 7 | D-82031 Grünwald
Geschäftsführer: Gitte Hansen, Julian Kropp
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pure11
clean room
consumables

pure11-Nr.: 052036b
Farbe: Weiß / Größe: 6,5 / Herst.-Nr.: 698763 / VE: 200 Paar

pure11-Nr.: 052037
Farbe: Weiß / Größe: 7,0 / Herst.-Nr.: 698764 / VE: 200 Paar

pure11-Nr.: 052037b
Farbe: Weiß / Größe: 7,5 / Herst.-Nr.: 698765 / VE: 200 Paar

pure11-Nr.: 052038
Farbe: Weiß / Größe: 8,0 / Herst.-Nr.: 698766 / VE: 200 Paar

pure11-Nr.: 052038b
Farbe: Weiß / Größe: 8,5 / Herst.-Nr.: 698767 / VE: 200 Paar

pure11-Nr.: 052039
Farbe: Weiß / Größe: 9,0 / Herst.-Nr.: 698768 / VE: 200 Paar

pure11-Nr.: 0520310
Farbe: Weiß / Größe: 10,0 / Herst.-Nr.: 698769 / VE: 200 Paar

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SHIELDskin XTREME™
A REVOLUTION IN GLOVE TECHNOLOGY

Sterile
BIO
CONTAMINATION CONTROL

SHIELDskin XTREME™
Sterile White Nitrile 330 DI+

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

CE
0123

ISO 374-1
Type B
JKP

ISO 374-5:2016
Level 3
VIRUS

Sterile

Bio contamination control

DI+

High contamination control

⇒ Powder-free triple DI washed hand-specific extra length (330 mm / 13.0") 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 - 10 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 8761	69 8762	69 8763	69 8764	69 8765	69 8766	69 8767	69 8768	69 8769

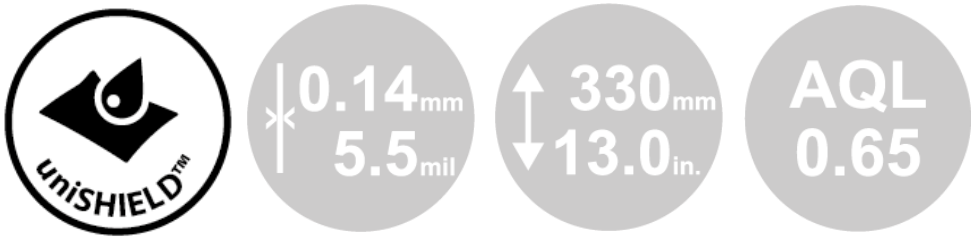
STANDARDS	
CE registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0123: TÜV Produkt Service, Germany.
EU PPE norms	ISO 21420:2020, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
EU 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	0.17	6.7	ASTM D3767-03 (2020)
⇒ Palm	0.14	5.5	
⇒ Cuff	0.10	3.9	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 330 mm / 13.0"	335 mm / 13.2"	ISO 21420:2020

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 6.0N	14 MPa	≥ 500%	9.0N	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	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
Chemicals	Performance: Type B (JKP). 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)

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	< 0.008	IEST-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.350	0.260	
Chloride (Cl)	0.350	0.260	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.050	0.009	
Nitrate (NO_3)	0.200	0.060	
Nitrite (NO_2)	0.050	< 0.008	
Phosphate (PO_4)	0.050	< 0.008	
Potassium (K)	0.100	0.040	
Sodium (Na)	0.100	0.040	
Sulphate (SO_4)	0.100	0.050	

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
ESD	Tested for electrostatic properties.	EN 1149-1/2/3 & 5
DNase and RNase contamination	DNase and RNase free.	MO BIO Certification

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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File: PDS_F_69876X_EN_SHIELDSKIN-XTREME_Sterile-White-Nitrile-330-DI-PLUS_EXT_FV_012_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

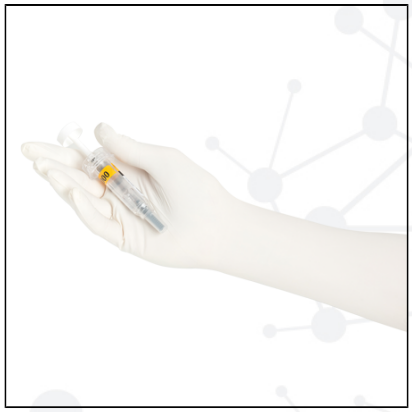
SHIELDskin XTREME* Sterile White Nitrile 330 DI+

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

CE 0123

ISO 374-1 Type B JKP

ISO 374-5:2016 Level 3 VIRUS



- Category III PPE glove (PPE Regulation (EU) 2016/425)
- Complex Design - For mortal & irreversible risks
- Powder-free white nitrile glove
- Hand-specific
- 330 mm / 0.14 mm (EN 420:2003+A1:2009)
- Biological risk (ISO 374-1:2016 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 JKP)
- Waterproof and for low chemical protection
- Tested for chemical permeation (EN 16523-1:2015+A1:2018)
- RNase and DNase free
- 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 1 min
79-06-1 Acrylamide 40%	LEVEL 6 480 min
1336-21-6 Ammonium Hydroxide 25%	LEVEL 1 27 min
75-09-2 Dichloromethane 99%	LEVEL 0 0 min
109-89-7 Diethylamine 99,5%	LEVEL 0 0 min
64-17-5 Ethanol 99.8%	LEVEL 1 16 min

64-17-5 Ethanol 70%	LEVEL 3 76 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
7722-84-1 Hydrogen Peroxide 30%	LEVEL 6 480 min
67-63-0 Isopropanol 100%	LEVEL 2 44 min
67-63-0 Isopropanol 70%	LEVEL 4 155 min
Mixed Solution Klercide Premier - WFI 60/40 sterile Alcohol	LEVEL 1 23 min
Mixed Solution Klercide Premier - WFI 70/30 sterile IPA	LEVEL 2 55 min
Mixed Solution Klercide 70/30 sterile IPA	LEVEL 3 94 min
80-62-6 Methyl Methacrylate 99%	LEVEL 0 1 min
142-82-5 n-Heptane 99%	LEVEL 2 56 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
108-95-2 Phenol aqueous solution 0.45%	LEVEL 6 480 min DR -14 %
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 95%-98%	LEVEL 0 6 min
7664-93-9 Sulphuric Acid 50%	LEVEL 6 480 min
1330-20-7 Xylene 98,5%	LEVEL 0 3 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 330 DI+
DESCRIPTION	Powder Free Extra DI washed Pair-packed Hand-specific 33cm Cleanroom Gloves
CLASSIFICATION	Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
69 8761	5.5
69 8762	6
69 8763	6.5
69 8764	7
69 8765	7.5
69 8766	8
69 8767	8.5
69 8768	9
69 8769	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 330 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: J, K & P), 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: 31th December 2019
Place: Bennekom
Validity of this declaration: 31th December 2019 until 31th December 2024

CHEMICAL ANALYTICAL SERVICES

TEST REPORT ASTM D 6978-05

Project No: 85202-A

SUBJECT: Permeation testing per ASTM D 6978-05 on sample submitted

SAMPLE: SHIELDskin™ Sterile Nitrile Gloves, 6 mil, lot# 274R08C
(equivalent SHIELDskin Xtreme™ Sterile White Nitrile 330 DI+ gloves (code 69 8761-69 8769)

Test Laboratory: Akron Rubber Development Laboratories Inc
2887 Gilchrist Road
Akron Ohio 44305
UNITED STATES

TESTING CHEMOTHERAPY DRUGS:

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

Test Chemical	Chemical Source	Lot #	Expiration date
Carmustine (BCNU)	Sigma	59H3657	09.2010
Cyclophosphamide (Cytoxan)	Sigma	068K1131	11.2010
Doxorubicin Hydrochloride	Teva	07N625	10.2009
Fluorouracil	APP	203933	04.2010
Etoposide (Toposar)	Teva	31303976B	09.2011
Paclitaxel (Taxol)	Dabur Oncology	PA08H00701	05.2010
Thiotepa	Sigma	078K1526	12.2010

COLLECTION MEDIA:
The collection media which were selected are listed in Table 2.

Table 2. Collection Media for Test Chemicals

Test Chemical	Concentration	Collection Medium
Carmustine (BCNU)	3.300 ppm	10% Ethanol Aqueous Solution
Cyclophosphamide (Cytoxan)	20.000 ppm	Distilled Water
Doxorubicin Hydrochloride	2.000 ppm	Distilled Water
Fluorouracil	50.000 ppm	9.20 pH Sodium Hydroxide Solution
Etoposide(Toposar)	20.000 ppm	Distilled Water
Paclitaxel (Taxol)	6.000 ppm	30% Methanol Aqueous Solution
Thiotepa	10.000 ppm	Distilled Water

NOTE: The chemotherapy drugs were prepared as required by the ASTM D 6978-05 Standard at 5.2.2.5, page 2, using the highest concentration of the drugs to which a healthcare worker might be exposed during handling as referenced in the most recent edition of the Physician's Desk Reference or the package inserts of the testing drugs.

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Deviation From Standard Test Method:	Used 1"(2.54cm) Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0° C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm^2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Palm area
Comments/Other Conditions:	Magnetic stir bar was used in the sampling chamber

DETECTION METHOD OF CHEMICAL PERMEATION; UV/VIS ABSORPTION SPECTROMETRY
Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristics wavelengths is shown in Table 3.

Table 3. Characteristics Wavelengths used in UV/VIS Absorption Spectrometry.

Test Chemical	**Wave length (nm)**
Carmustine (BCNU)	229
Cyclophosphamide (Cytoxan)	200
Doxorubicin Hydrochloride	232
Fluorouracil	269
Etoposide (Toposar)	205
Paclitaxel (Taxol)	231
Thiotepa	199

SAMPLE CHARACTERISTICS

Table 4. Thickness Characteristics

SAMPLE	THICKNESS (mm)				WEIGHT/UNIT AREA (g/m^2)
	#1	#2	#3	Average	
Carmustine (BCNU)	0.109	0.108	0.113	0.110	108.1
Cyclophosphamide (Cytoxan)	0.107	0.111	0.115	0.111	108.1
Doxorubicin Hydrochloride	0.114	0.111	0.111	0.112	108.1
Fluorouracil	0.111	0.106	0.115	0.111	108.1
Etoposide (Toposar)	0.102	0.110	0.110	0.107	108.1
Paclitaxel (Taxol)	0.106	0.109	0.112	0.109	108.1
Thiotepa	0.104	0.105	0.119	0.109	108.1

CALCULATION:

Average permeation rate for each sampling time interval (except time = 0 minutes) was calculated using the equation below:

$$P_i = ((C_i - C_{i-1}) \times V_t) \; / \; ((T_i - T\,C_{i-1}) \times A)$$

Where:

P_i = average permeation rate, ug/cm2/min. at time interval T_i - T_{i-1}
C_i = concentration of test chemical detected in collection medium, ug/l,at time T_i
V_t = volume of collection medium, l
i = an index number starting with i = 1 for the first sample
T_i = sampling time, minutes
A = area of specimen in contact with the test chemical, cm^2

RESULTS

Table 5. Permeation Test Results:

Test Chemical	Average Breakthrough* Detection Time	Average Steady State Permeation Rate
	Minutes	(Avg.)µg/cm^2/min.
Carmustine (BCNU) 3,300 ppm/ 3.3 mg/ml	4.99 (5.45, 4.67, 4.84)	0.840 (0.710, 0.515, 01.30)
Cyclophosphamide (Cytoxan) 20,000 ppm/ 20.0 mg/ml	No breakthrough was detected up to 240 minutes	0
Doxorubicin Hydrochloride 2,000 ppm/ 2.0 mg/ml	No breakthrough was detected up to 240 minutes	0
Fluorouracil 50,000 ppm/ 50.0 mg/ml	No breakthrough was detected up to 240 minutes	0
Etoposide (Toposar) 20,000 ppm/ 20.0 mg/ml	No breakthrough was detected up to 240 minutes	0
Paclitaxel (Taxol) 6,000 ppm/ 6.0 mg/ml	No breakthrough was detected up to 240 minutes	0
Thiotepa 10,000 ppm/ 10.0 mg/ml	120.3 (147.0, 17.37, 196.61)	0.159 (0.072, 0.325, 0.080)

*Breakthrough detection time is the time in minutes measured from the start of the test to the sampling time that immediately precedes the sampling time at which the permeation rate reaches 0.01 µg/ **cm**^{2}/min.

SHIELD Scientific B.V.
Date: 20.05.2010

Cisco Robles
General Manager