SHIELD Scientific B.V.

SHIELDskin Orange Nitrile 300

pure¹¹-Nr.: 1105306, Marke: SHIELD Scientific B.V.

Eigenschaften

- Antistatisch
- AQL (Acceptable Quality Level)-Wert: 0,25
- Chemikalienbeständig gegen Aceton: Level 0 (<10min)
- Chemikalienbeständig gegen Isopropanol (100%): Level 2 (30-60min)
- Chemikalienbeständig gegen Isopropanol (70%): Level 3 (60-120min)
- Chemikalienbeständigkeit - Typ: Typ B
- Handschuhtyp: Dünnfilm
- Länge in cm: 30 cm
- Länge in Inches: 11,8 In
- Latexfrei
- Material: Nitril/Neopren
- Materialzusammensetzung: Mischmaterial
- Oberflächenbeschaffenheit: glatt
- Puderfrei
- Reißfestigkeit EN 455-2 ASTM in MPa: 10-20
- Rollrand
- Schutz vor Blut und Körpersekreten ISO 16604:2004
- Texturierte Fingerspitzen
- Passform Hand: beidhändig

Empfohlene Reinraumklassen

ISO 7 | 8 | 9

GMP D

pure¹¹ GmbH |
Bavariafilmplatz 7 | D-82031 Grünwald
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www.pure11.de
info@pure11.de

- Verpackungsform: Spenderbox
- Viren-/Mikroorganismenschutz EN ISO 374-5:2016
- Vulkanisationsbeschleunigerfrei
- Wandstärke Mittelfinger in mm: 0,17 mm
- Zytostatikageeignet
- Marke: SHIELD Scientific B.V.

Material

- Nitril/Neopren

Verpackung

- 500STK

Produktvarianten

pure¹¹-Nr.: 1105306ORL, SHIELDskin Orange Nitrile 300

Farbe: Orange; Größe: L / VE: 500STK

pure¹¹-Nr.: 1105306ORM, SHIELDskin Orange Nitrile 300

Farbe: Orange; Größe: M / VE: 500STK

pure¹¹-Nr.: 1105306ORS, SHIELDskin Orange Nitrile 300

Farbe: Orange; Größe: S / VE: 500STK

pure¹¹-Nr.: 1105306ORXL, SHIELDskin Orange Nitrile 300

Farbe: Orange; Größe: XL / VE: 500STK

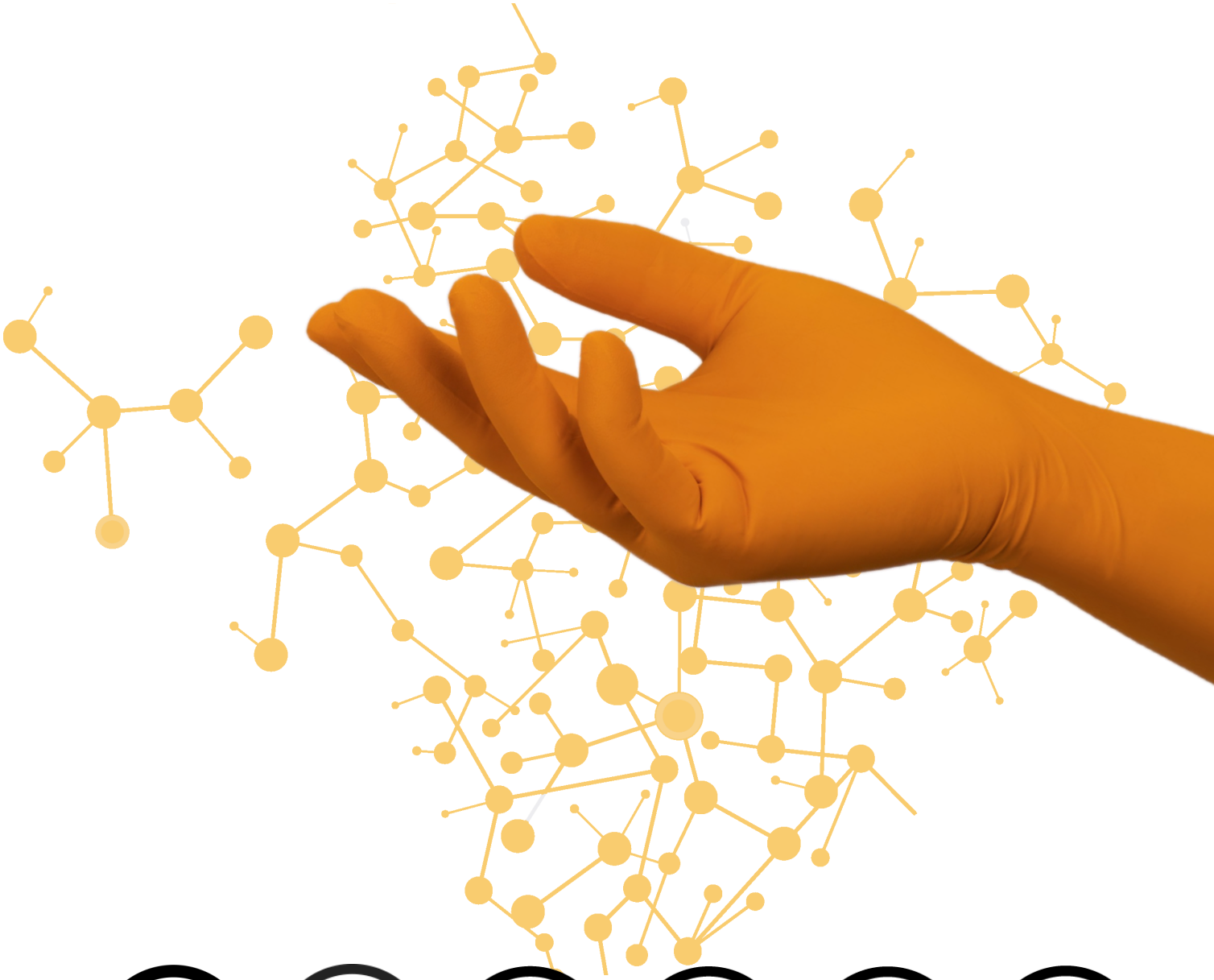
pure¹¹-Nr.: 1105306ORXS, SHIELDskin Orange Nitrile 300

Farbe: Orange; Größe: XS / VE: 500STK

SHIELDskin™
A REVOLUTION IN GLOVE TECHNOLOGY

ORANGE
BIOLOGISCHES RISIKO

SHIELDskin™
ORANGE NITRILE™ 300



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

MDR Medical Device Class I REGULATION (EU)2017/745

CE 0598

UK CA 0120

ISO 374-1 Type B JKPT

ISO 374-5:2016 Level 3 VIRUS

★★★★★ Generelle Risiken

★★★★★ Biologisches Risiko

★★★☆☆ Chemikalien Risiko

⇒ Unsteriler Schutzhandschuh aus Nitril/Neopren, puderfrei, beidhändig tragbar, extra lange Ausführung (300 mm / 11.8").

⇒ Persönliche Schutzausrüstung KAT III (PSA - Komplexes Design) gemäss Verordnung (EU) 2016/425.

⇒ Registriert als Klasse 1 (MPD) gemäss Medizin Produkte Verordnung (EU) 2017/745.

⇒ In völliger Übereinstimmung mit der neuesten EU PSA Norm zum Schutz gegen Chemikalien, Mikroorganismen und Viren.

BESCHREIBUNG	
Bestandteile	Nitril und Neopren (*Polychloropren und Acrylonitril butadien*).
Design	Orange, beidhändig tragbar, Rollrand, texturierte Fingerspitzen.
Verpackung	50 Handschuhe per Box - 10 Boxen per Karton = 500 Handschuhe.

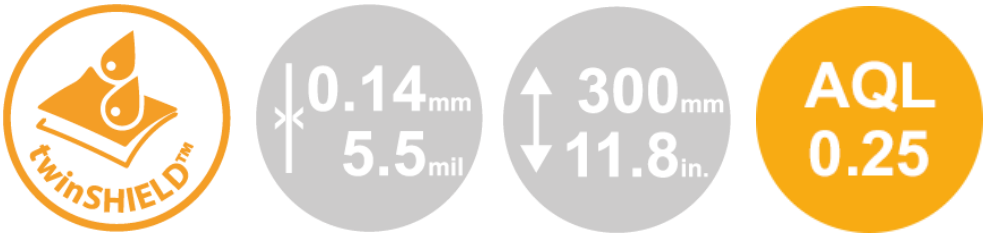
GRÖSSEN	6/XS	7/S	8/M	9/L	10/XL	11/XXL
Artikel Nr.	67 6251	67 6252	67 6253	67 6254	67 6255	67 6256

NORMEN	
CE/UKCA registrierung	PSA Kategorie III (Komplexes Design) - Verordnung (EU) 2016/425. CE Notified Body No 0598: SGS Fimko Oy, Helsinki - Finnland. UKCA Notified Body No 0120: SGS United Kingdom Ltd, Ellesmere port - United-Kingdom. MP Klasse 1 - Verordnung (EU) 2017/745.
EU PSA normen	ISO 21420:2020+A1:2022, EN 421:2010, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374 -4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 und ISO 16604:2004 Verfahren B.
EU MP normen	EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 und EN 455-4:2009.
US standards	ASTM D3767-03 (2020), ASTM D573-04 (2019), ASTM D412-16, ASTM D6978-05 (2019).
Weitere standards	EN1149-1/2/3 & 5, ISO 21171:2006, ISO 10993-10:2021.

QUALITÄT	
Qualitätssicherung	Produktionsmanagement gemäss ISO 9001:2015 und ISO 13485:2016. Umweltmanagementsysteme gemäss ISO 14001:2015.
Technologie	twinSHIELD™ doppelwandiger Schutz für einen stärkeren Handschuh und reduziertem Risiko von Mikrolöchern. 2-farbig: orange, zur vereinfachten Auswahl des Handschuhes gemäss des Risikos, kombiniert mit einer sehr angenehmen, weichen Innenlage.

DOKUMENTATION	
Konformitätserklärung	Diese Dokumente können kostenlos von der Produktseite auf unserer Website heruntergeladen werden: www.shieldscientific.com. Für einen einfachen Zugriff scannen Sie den QR-Code.
EU baumuster-prüfbescheinigung	
Benutzerhinweis	

PHYSIKALISCHE EIGENSCHAFTEN



NOMINALE WANDSTÄRKE	mm[1]	mil	Norm
⇒ Finger	0.17	6.7	ASTM D3767-03 (2020)
⇒ Handfläche	0.14	5.5	
⇒ Stulpe	0.10	3.9	

[1] *Wandstärke (+/- 0.03 mm)*

LÄNGE	Minimum	Typischer Wert	Norm
⇒ Spitze Mittelfinger bis Ende Stulpe	≥ 290 mm / 11.4"	300 mm / 11.8"	ISO 21420:2020+A1:2022

REIßFESTIGKEIT	Reißfestigkeit (Spez.)		Äusserste Dehnbarkeit (Spez.)	Reißfes-tigkeit (typischer Wert)	Norm
⇒ Vor Alterung	≥ 6.0N	14 MPa	≥ 500%	10.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ Nach Alterung	≥ 6.0N	14 MPa	≥ 400%	8.0N	

FESTSTELLUNG "PINHOLES"	Leistungsnachweis	Norm
⇒ Acceptable Quality Level (AQL)	< 0.25[2] - Level 3	ISO 374-2:2019 EN 455-1:2020

[2] *AQL gemäss Definition ISO 2859-1:1999 Probenentnahme.*

SCHUTZLEISTUNG

RISIKEN	Beschreibung	Norm
Mikroorganismen	1000 ml Wasser Test. Leistungslevel 3, AQL < 0.25 (Inspektionslevel G1).	ISO 374-2:2019
Viren	Viren Penetrationstest mit Phi-X174 Bacteriophage gemäss ISO 16604:2004 Verfahren B.	ISO 374-5:2016
Chemikalien	Leistung: Typ B (JKPT). Permeation: Intensiv getestet. Chemikalienbeständigkeitsliste online unter: www.shieldscientific.com. Degradation: auf Degradationsbeständigkeit mit Chemikalien getestet.	ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018 ISO 374-4:2019
Radioaktivität	Schutz vor radioaktiver Kontamination.	EN 421:2010
Zytostatika substanzen	Auf Permeation getestet mit Zytostatika Substanzen durch Dauerkontakt mit der Substanz.	ASTM D6978-05 (2019)
ESD	Antistatisches Verhalten getestet.	EN 1149-1/2/3 & 5

ALLERGIEN	
Bio kompatibilität	Nachgewiesen durch Primary Skin Irritation und Sensitatzions Test gemäss ISO 10993-10:2021 Test.
Vulkanisations-bescheleuniger	Vulkanisationsbeschleuniger frei. Reduziert das Risiko einer Kontakt Dermatitis (Typ IV Allergie/Chemikalien Allergie).
Chemikalien allergie	Nicht nachweisbare Level durch wasserlösliche Extraktion (Phosphate gepufferte Lösung) und High Performance Chromotography (HPLC) Proben Methode für quantitative Analyse.
Puderrück-standswerte	Puderfrei, reduziert die Gefahr auf von Puder verursachter Dermatitis. Puderrückstände (typischer Wert) nicht mehr als 1 mg/HS (Limit = 2 mg/HS) (ISO 21171:2006).
Latex proteine	Latex frei.

SHIELD Scientific
compliance comfort protection
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File: PDS_F_67625X_DE_SHIELDSKIN_ORANGE-NITRILE-300_EXT_FV_018_30062024_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 > 29 min	30 > 59 min	60 > 119 min	120 > 239 min	240 > 479 min	> 480 min

SHIELDskin™ ORANGE NITRILE™ 300

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

MDR Medical Device: Class I REGULATION (EU)2017/745

CE 0598

ISO 374-1 Type B JKPT

- Length: 300 mm/ 11.8"
- Palm thickness: 0.14 mm/ 5.5 mil
- Chemical performance: Type B
- Biological risk: AQL 0.25 / Level 3
- Particles level: N/A / N/A
- Virus resistant / Chemotherapy drugs
- Allergies: Latex-free / Accelerator-free
- Design: Ambidextrous / Powder-free
- Colour: Orange (outer)/ White (inner)
- ESD - Static dissipative
- Mechanical risk: N/A
- Applications: Laboratory / General workplace / Healthcare

96-48-0 Butyrolactone	LEVEL 2 49 min
7761-88-8 Silver nitrate 15%	LEVEL 6 480 min
67-63-0 Isopropanol 70% at 23°C	LEVEL 3 66 min
79-21-0 Peracetic Acid 10%	LEVEL 4 160 min
5329-14-6 Sulfamic Acid 15%	LEVEL 6 480 min
7550-35-8 Lithium bromide 30%	LEVEL 6 480 min DR 22%
7697-37-2 Nitric acid 65%	LEVEL 1 10 min

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108-95-2 Phenol aqueous solution 0.45%	LEVEL 6 480 min DR 35%
79-08-3 Bromoacetic acid 7.5%	LEVEL 4 209 min
64-19-7 Acetic acid 99%	LEVEL 0 8 min
67-56-1 Methanol 20%	LEVEL 3 75 min
Mixed Solution LiPF6	LEVEL 6 480 min
584-84-9 Toluene diisocyanate 95%	LEVEL 0 0 min
64742-49-0 Petroleum benzene 80-100°C	LEVEL 6 480 min
Mixed Solution Neopredisan 135-1	LEVEL 1 20 min
548-62-9 Crystal violet	LEVEL 6 480 min
95-54-4 O-Phenylenediamine	LEVEL 5 308 min
108-95-2 Phenol 4%	LEVEL 1 22 min
72-57-1 Trypan blue	LEVEL 6 480 min
314-13-6 Evans blue	LEVEL 6 480 min
91-95-2 Diaminobenzidine	LEVEL 6 480 min

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3761-53-3 Ponceau 2R	LEVEL 6 480 min
6226-79-5 Ponceau S	LEVEL 6 480 min
Mixed Solution Phenol:Chloroform Isoamyl Alcohol 25:24:1	LEVEL 0 1 min
123-38-6 Propionaldehyde 97%	LEVEL 0 2 min
Mixed Solution Bacillol AF	LEVEL 2 50 min
Mixed Solution Bacillol 30 Foam	LEVEL 3 73 min
66-81-9 Cycloheximide	LEVEL 6 480 min
Mixed Solution Hydranal ® -Composite 2	LEVEL 6 480 min
8007-56-5 Aqua regia	LEVEL 6 480 min
Mixed Solution Euro 95 unleaded petrol	LEVEL 1 10 min
Mixed Solution Mucocit®-T branded mixture	LEVEL 6 480 min
50-01-1 Guanidine hydrochloride	LEVEL 6 480 min
127-18-4 Tetrachloroethylene 99%	LEVEL 0 5 min
10127-02-3 Acridine orange	LEVEL 6 480 min

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111-76-2
2-Butoxyethanol 99%
LEVEL 1
23 min

108-20-3
Diisopropyl ether 99%
LEVEL 1
16 min

79-10-7
Acrylic acid 99%
LEVEL 0
4 min

7726-95-6
Bromine
LEVEL 0
6 min

37143-54-7
1-Methoxy-2-propylamine 95%
LEVEL 0
3 min

108-67-8
1,3,5-Trimethylbenzene 98%
LEVEL 1
10 min

60-24-2
2-Mercaptoethanol 99%
LEVEL 0
1 min

95-63-6
1,2,4- Trimethylbenzene 98%
LEVEL 1
13 min

75-56-9
Propylene oxide 99%
LEVEL 0
0 min

7803-57-8
Hydrazine monohydrate 98%
LEVEL 4
180 min

78-83-1
Isobutanol 99%
LEVEL 3
76 min

77-86-1
Tris (hydroxymethyl) aminomethane Sat. solution
LEVEL 6
480 min

598-75-4
Secondary isoamyl alcohol 98%
LEVEL 2
55 min

127-09-3
Sodium acetate Sat. solution
LEVEL 6
480 min

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7664-93-9 Sulphuric Acid 50%	LEVEL 6 480 min
7664-93-9 Sulphuric Acid 95%-98%	LEVEL 0 8 min
108-87-2 Methylcyclohexane 99.9%	LEVEL 2 55 min
62-53-3 Aniline 99.9%	LEVEL 1 14 min
97-88-1 Butyl methacrylate 99.9%	LEVEL 1 11 min
96-47-9 2-Methyltetrahydrofuran 99.9%	LEVEL 0 1 min
67-68-5 Dimethyl sulfoxide 99% (DMSO)	LEVEL 2 48 min
75-12-7 Formamide 99%	LEVEL 3 99 min
108-95-2 Phenol 0.1% solution	LEVEL 6 480 min
75-59-2 Tetramethylammonium hydroxide 2.5%	LEVEL 6 480 min
109-66-0 n-Pentane 98%	LEVEL 2 56 min
108-94-1 Cyclohexanone 99%	LEVEL 0 6 min
110-54-3 n-Hexane 95%	LEVEL 3 97 min
71-23-8 n-Propanol	LEVEL 2 46 min

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127-19-5
Dimethyl acetamide 99%
LEVEL 1
10 min

60-29-7
Diethyl ether 99%
LEVEL 0
2 min

75-15-0
Carbon disulfide 99.9%
LEVEL 0
0 min

108-39-4
m-Cresol 98.5%
LEVEL 2
59 min

76-03-9
Trichloroacetic acid 10%
LEVEL 6
480 min

7803-57-8
Hydrazine monohydrate 80%
LEVEL 6
480 min

1634-04-4
Methyl Tert Butyl Esther (MTBE)
LEVEL 1
11 min

7664-93-9
Sulphuric Acid 10%
LEVEL 6
480 min

76-05-1
Trifluoroacetic acid 99%
LEVEL 0
1 min

67-64-1
Acetone 99.8%
LEVEL 0
1 min

7681-52-9
Sodium Hypochlorite 13%
LEVEL 6
480 min

1310-58-3
Potassium Hydroxide 40%
LEVEL 6
480 min

54-11-5
Nicotine 98%
LEVEL 4
151 min

67-63-0
Isopropanol 70%
LEVEL 3
72 min

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7722-84-1 Hydrogen peroxide 12%	LEVEL 6 480 min
77-92-9 Citric acid 30%	LEVEL 6 480 min
1330-20-7 Xylene 98.5%	LEVEL 0 4 min
121-44-8 Triethylamine 99%	LEVEL 2 36 min
108-88-3 Toluene 99.9%	LEVEL 0 1 min
109-99-9 Tetrahydrofuran 99.9%	LEVEL 0 0 min
100-42-5 Styrene 99.9%	LEVEL 0 0 min
1310-73-2 Sodium Hydroxide 50%	LEVEL 6 480 min
1310-73-2 Sodium Hydroxide 40%	LEVEL 6 480 min DR -7%
110-86-1 Pyridine	LEVEL 0 1 min
7664-38-2 Phosphoric acid 85%	LEVEL 6 480 min
7664-38-2 Phosphoric Acid 30%	LEVEL 6 480 min
108-95-2 Phenol 50%	LEVEL 1 24 min
7697-37-2 Nitric Acid 70%	LEVEL 0 5 min

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7697-37-2 Nitric Acid, 50%	LEVEL 3 63 min
872-50-4 N-methyl-2-pyrrolidone	LEVEL 2 32 min
80-62-6 Methyl Methacrylate 99%	LEVEL 0 3 min
75-09-2 Dichloromethane 99%	LEVEL 0 0 min
108-10-1 Methyl Isobutyl Ketone 99%	LEVEL 0 2 min
67-56-1 Methanol 99.9%	LEVEL 0 6 min
67-63-0 Isopropanol 100%	LEVEL 2 54 min
540-84-1 Iso-Octane 99%	LEVEL 6 480 min
7722-84-1 Hydrogen peroxide 30%	LEVEL 6 480 min DR 27%
7664-39-3 Hydrofluoric acid 48%	LEVEL 0 6 min
7664-39-3 Hydrofluoric acid 40%	LEVEL 1 14 min
7647-01-0 Hydrochloric acid 37%	LEVEL 4 141 min
999-97-3 Hexamethyldisilizan 99%	LEVEL 6 480 min
142-82-5 n-Heptane 99%	LEVEL 3 91 min DR 47%

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111-30-8 Glutaraldehyde 25%	LEVEL 6 480 min
64-18-6 Formic acid 98.5%	LEVEL 0 4 min
50-00-0 Formaldehyde 37%	LEVEL 6 480 min DR 36%
50-00-0 Formaldehyde 10%	LEVEL 6 480 min
141-78-6 Ethyl acetate 99.8%	LEVEL 0 1 min
1239-45-8 Ethidium bromide 5%	LEVEL 6 480 min
64-17-5 Ethanol 70%	LEVEL 2 34 min
64-17-5 Ethanol 99.8%	LEVEL 1 22 min
68-12-2 Dimethyl formamide 99%	LEVEL 0 5 min
109-89-7 Diethylamine 99.5%	LEVEL 0 1 min
110-82-7 Cyclohexane	LEVEL 6 480 min
67-66-3 Chloroform 99.8%	LEVEL 0 0 min
71-36-3 Butanol 100%	LEVEL 2 47 min
74-97-5 Bromochloromethane	LEVEL 3 79 min

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100-51-6 Benzyl alcohol	LEVEL 1 11 min
1336-21-6 Ammonium hydroxide 25%	LEVEL 2 33 min
107-13-1 Acrylonitrile 99%	LEVEL 0 0 min
79-06-1 Acrylamide 40%	LEVEL 6 480 min
75-05-8 Acetonitrile 99.9%	LEVEL 0 1 min
107-06-2 1,2-Dichloroethane 99%	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.

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SHIELD Scientific compliance comfort protection		EU DECLARATION OF CONFORMITY	
Originator: J.F ROBLES	**Revision N°:** 016	**Revision date:** 13.11.2024	**Validity date:** 26/02/2025

Product	SHIELDskin™ ORANGE NITRILE™ 300
Description	Powder-free extra length ambidextrous non-sterile 30 cm nitrile gloves
Classification	Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

Product codes	Sizes
67 6251	6/XS
67 6252	7/S
67 6253	8/M
67 6254	9/L
67 6255	10/XL
67 6256	11/XXL
N/A	N/A
N/A	N/A
N/A	N/A

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™

ORANGE NITRILE™ 300

is in conformity with the provisions of the Medical Device Regulation (EU) 2017/745 and with the national standards transposing harmonized standards EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015 & EN 455-4:2009 . It is selfcertified as a Medical Device Class 1. Single Registration Number (SRN) NL-MF-000001691 and Basic UDI-DI 87196320767625XXN refer.

is in conformity with the provisions of Regulation (EU) 2016/425 and with the harmonized standards EN ISO 374-1:2016 + A1:2018 (as a Type B glove against reagents: J, K, P & T) EN ISO 374-5:2016 & EN 420:2003+A1:2009 as well as test method ISO 374-2:2019 (performance level 3), including protection against viruses (ISO 16604:2004), EN 16523-1:2015 + A1:2018 & EN ISO 374-4:2019. . This device is identical to the PPE, which is the subject of EU Type Examination (Module B) certificate of conformity no. FI18/962117 issued by the Notified Body:

SGS FIMKO OY (Notified Body No: 0598) Takomotie 8, FI-00380 Helsinki, Finland

This device is subject to the procedure set out in Annex VIII (ModuleC2) of the Regulation under the surveillance of the Notified Body:

SGS FIMKO OY (Notified Body No: 0598) Takomotie 8, FI-00380 Helsinki, Finland

J.F ROBLES
General Manager
Date: 13.11.2024
Place: Bennekom

SHIELD Scientific compliance comfort protection