



## duoSHIELD Ice Nitrile 240

pure<sup>11</sup>-Nr.: 05302, Hersteller: Shield Scientific

### Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105302
- Material: Nitril
- Beidhändig tragbar
- Puderfrei
- Latexfrei
- AQL-Wert (Acceptable Quality Level): 1.5
- Texturierte Fingerspitzen
- Reduziertes Allergierisiko (Type I & Type IV)
- Viren- und mikroorganismenresistent

### Empfohlene Reinraumklassen

ISO  3  4  5  6  7  8  9

GMP       D

### Produktvarianten

**pure<sup>11</sup>-Nr.: 05302XS**

Farbe: Blau / Größe: XS / Herst.-Nr.: 655121 / VE: 1.000 Stück

**pure<sup>11</sup>-Nr.: 05302S**

Farbe: Blau / Größe: S / Herst.-Nr.: 655122 / VE: 1.000 Stück

**pure<sup>11</sup>-Nr.: 05302M**

Farbe: Blau / Größe: M / Herst.-Nr.: 655123 / VE: 1.000 Stück

**pure<sup>11</sup>-Nr.: 05302L**

Farbe: Blau / Größe: L / Herst.-Nr.: 655124 / VE: 1.000 Stück

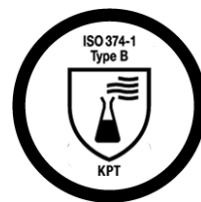
**pure<sup>11</sup>-Nr.: 05302XL**

Farbe: Blau / Größe: XL / Herst.-Nr.: 655125 / VE: 1.000 Stück

Quelle: <https://www.pure11.de/duoshield-ice-nitrile-240>

# duoSHIELD™

## ICE NITRILE™ 240





**Dual  
risk**

- ⇒ Powder-free ambidextrous standard length (240 mm / 9.4") non-sterile nitrile exam gloves.
- ⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.
- ⇒ Medical Device Class 1 (MDR) according to the Regulation (EU) 2017/745.
- ⇒ Fully compliant to the latest EU PPE norms relating to protective gloves against chemicals, micro-organisms and viruses.

DESCRIPTION	
Formulation	Nitrile synthetic rubber ( <i>acrylonitrile butadiene</i> ).
Design	Ice blue, ambidextrous, beaded cuff, textured fingertips.
Packaging	100 gloves per dispenser - 10 dispensers per carton.

SIZES	6/XS	7/S	8/M	9/L	10/XL
Codes	65 5121	65 5122	65 5123	65 5124	65 5125

STANDARDS	
CE registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND. MDR Class 1 - Regulation 2017/745.
EU PPE norms	ISO 21420:2020, 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 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.
Other standards	ISO 21171:2006, 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.

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	



# PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm <sup>1</sup>	mil	Norm
⇒ Finger	0.14	5.5	ASTM D3767-03 (2020)
⇒ Palm	0.11	4.3	
⇒ Cuff	0.08	3.1	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 240 mm / 9.4"	242 mm / 9.5"	ISO 21420:2020 EN 455-2:2015

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 9.0N	19 MPa	≥ 500%	12.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ After aging	≥ 9.0N	18 MPa	≥ 400%	10.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 1.5 <sup>2</sup> - Level 2	EN 455-1:2000 ISO 374-2:2019

<sup>2</sup> AQL as defined per ISO 2859-1:1999 for sampling by attributes.

# PROTECTION PROPERTIES

RISKS	Description	Norm
Micro-organisms	1000 ml water test. Performance level 2, AQL < 1.5 (inspection level G1).	EN 455-1:2000 ISO 374-2:2019
Viruses	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
Chemicals	<u>Performance</u> : Type B (KPT). <u>Permeation</u> : 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
Radioactivity	Protection from radioactive contamination.	EN 421:2010
Fit for special purpose	Size and length: Sizes 10 (XL) and 9 (L) gloves are shorter in length than that required by ISO 21420:2020. These gloves are intended for use in light-duty manufacturing and industrial applications where the demand for the advantages of a shorter glove outweighs the need for additional length.	ISO 21420:2020

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.
Residual powder	Powder-free to minimize the potential consequences of powder-borne dermatitis. Residual powder content is 1.0 mg/glove (typical) with a limit of 2.0 mg/glove (ISO 21171:2006).
Latex protein	Latex-free.

# CHEMICAL RESISTANCE GUIDE



## duoSHIELD\* ICE NITRILE\* 240



- Class 1 MDR glove (Regulation (EU) 2017/745)
- Category III PPE glove (PPE Regulation (EU) 2016/425)
- Complex Design - For mortal and irreversible risks
- Powder-free blue nitrile glove
- Ambidextrous
- 240 mm / 0.11 mm (EN 455-2:2015 and ISO 21420:2020)
- Biological risk (ISO 374-5:2016 VIRUS)
- Micro-organism resistant - AQL < 1.5 (ISO 374-2:2019 Level 2 and EN 455-1:2000)
- Virus resistant (ISO 16604:2004 Procedure B)
- Tested for chemical permeation - Type B KPT according to ISO 374-1:2016+A1:2018
- EN 16523-1:2015+A1:2018 chemical testing method
- Type I hypersensitivity eliminated - Type IV hypersensitivity reduced

1239-45-8 Ethidium bromide 5%	<b>LEVEL 6</b> 480 min
50-00-0 Formaldehyde 37%	<b>LEVEL 6</b> 480 min
7722-84-1 Hydrogen peroxide 30%	<b>LEVEL 3</b> 61 min
1310-73-2 Sodium Hydroxide 40%	<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.



**SHIELD Scientific**  
compliance comfort protection

## EU DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES AND PERSONAL PROTECTIVE EQUIPEMENT

Originator: J.F ROBLES

Revision: 7

Revision date: 31.12.2019

Validity date: 31.12.2024

<b>PRODUCT</b>	duoSHIELD™ ICE NITRILE 240
<b>DESCRIPTION</b>	Powder Free Ambidextrous Non-Sterile 24 cm Nitrile Gloves
<b>CLASSIFICATION</b>	Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
65 5121	6/XS
65 5122	7/S
65 5123	8/M
65 5124	9/L
65 5125	10/XL

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:

### duoSHIELD™ ICE NITRILE 240

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. 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