

## Nitril-Handschuh

Puderfreier, leichter Nitril-Handschuh für die Verwendung  
u.a. in Pflege, Laboren, Lebensmittelherstellung/-verarbeitung und Kosmetik.

**Handelsname:** Puderfreier Nitril-Handschuh

**Hersteller:** Semperit Technische Produkte GmbH

## Nitril-Handschuh



[www.bauer-karlsruhe.de](http://www.bauer-karlsruhe.de)

## Nitril-Handschuh

### Konformitätserklärung Lebensmittelkontakt

**sempermed®**   
A MEMBER OF THE SEMPERIT-GROUP

#### Declaration of Compliance for Food Contact

Regulation (EC) No. 1935/2004 materials and articles intended to come into contact with food

We

**Semperit Technische Produkte Ges.m.b.H.**  
**Modecenterstrasse 22**  
**1030 Vienna**  
**Austria**

authorized EC representative of the manufacturer

**Semperit Investments Asia Ltd,**  
**8 Jurong Town Hall Road**  
**#29-03 to 06 JTC Summit**  
**Singapore 609434,**

declares the product identified hereafter as:

#### **Semperguard® Sapphire Blue**

(a single-use glove made from nitrile butadiene rubber latex)

is compliant to the following regulations and national laws:

- **REGULATION (EC) No 1935/2004** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- **German Recommendation XXI** for the health-related evaluation of materials and object for the food contact with foodstuffs, of 01 July 2016, in the frame of the German Foods, Consumer Goods and Feedstuffs Code, § 31 (1)
- **COMMISSION REGULATION (EC) No 2023/2006** of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food

This declaration has a validity of 2 years, subject to unexpected legal modifications.

Semperit Investment Asia Pte Ltd, 8 Jurong Town Hall Road, #29-03 to 06 JTC Summit,  
609434 Singapore | Semperit Technische Produkte Gesellschaft m.b.H.,  
Modecenterstraße 22, 1030 Vienna, Austria  
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## Nitril-Handschuh Konformitätserklärung Lebensmittelkontakt

**sempermed**<sup>®</sup>  
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### INFORMATION OF DUAL-USE ADDITIVES

E-Number	Substance	Specific Maximum Level*	Specific Migration Level**
E 171	Titanium dioxide	quantum satis	no limit
E 470a	Sodium, potassium and calcium salts of fatty acids	quantum satis	no limit
E 471b	Magnesium salts of fatty acids	quantum satis	no limit

\* in mg/kg food according to (EU) 1129/2011

\*\* in mg/kg food according to (EU) 10/2011

### SPECIFICATIONS ON THE USE OF THE ARTICLE

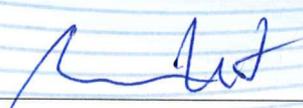
- Type(s) of food intended to be used with the product:  
All types of food.
- Time and temperature for contact with the food:  
Duration: 10min  
Temperature: 40°C
- Ration of food contact surface area to volume used to establish the compliance of the material or article:  
1.6 dm<sup>2</sup> · kg<sup>-1</sup>

### INFORMATION ON THE USE OF A FUNCTIONAL BARRIER

No functional barrier is used in this article.

Thus, the mentioned products may be used safely for the preparation and handling of foodstuffs and may stand in direct contact with all types of food for a short period of time up to 10 minutes at 40°C.

Issued: 15 January 2020

  
Dr. Alexander Weinert  
Head of Technical Product Management



  
Margit Wallisch  
Technical Product Manager

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## Nitril-Handschuh

### Konformitätserklärung

Medizinprodukte Verordnung / PSA-Verordnung



### KONFORMITÄTSERKLÄRUNG

MEDIZINPRODUKTEVERORDNUNG (EU) 2017/745  
VERORDNUNG (EU) 2016/425 FÜR PERSÖNLICHE SCHUTZAUSRÜSTUNG

Hersteller

**Semperit Investments Asia Pte. Ltd.**  
8 Jurong Town Hall Road,  
#29-03 to 06 The JTC Summit,  
Singapore 609434, Singapore  
sempermed@semperitgroup.com  
SRN: SG-MF-000001645

EU-Bevollmächtigter

**Semperit Technische Produkte Gesellschaft m.b.H.**  
Triester Bundesstraße 26, 2632 Wimpassing, Austria  
sempermed@semperitgroup.com  
SRN: AT-AR-000000735

Dieses Zertifikat ist gültig für die folgenden Produkte:

**Nicht-steriler Untersuchungs- und Schutzhandschuh für den Einmalgebrauch**

Klassifizierung: Klasse I gemäß Medizinprodukteverordnung (EU) 2017/745  
Kategorie III gemäß PSA Verordnung (EU) 2016/425

Basic UDI-DI: 9001570N\*F-030VB-N-3RB

#### semperguard sapphire blue

Größen	X-Small	Small	Medium	Large	X-Large
Artikelnummern	-	3000006819	3000006820	3000006821	3000006822
	-	3000006815	3000006816	3000006817	3000006818

**Wir bestätigen hiermit unter alleiniger Verantwortung, dass die CE gekennzeichneten Produkte mit den Anforderungen der Medizinprodukteverordnung (EU) 2017/745 übereinstimmen.**

Erklärung basierend auf Anhang IV. Klassifizierung gemäß Regel 5, Anhang VIII. Konformitätsbewertung gemäß Anhang II.

Angewandte Normen: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

**Wir bestätigen hiermit unter alleiniger Verantwortung, dass die oben genannten CE gekennzeichneten Produkte mit den maßgeblichen Bestimmungen der Verordnung (EU) 2016/425 für Persönliche Schutzausrüstung übereinstimmen und Gegenstand sind der EU-Baumusterprüfbescheinigung Nr. 2777/11466-01/E03-01 ausgestellt durch:**

**SATRA Technology Europe Ltd, ID No. 2777**  
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Die Produkte sind Gegenstand der Verfahren gemäß Annex VII (Module C2) der Verordnung unter Aufsicht von **SATRA Technology Europe Ltd, ID No. 2777**  
Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland

Angewandte Normen: EN 420:2003+A1:2009, ISO 374-1:2016/AMD 1:2018, EN 374-2:2014, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016, ISO 2859-1:1999 AMD 1:2011

Ausgestellt am: Singapore, 2022-01-10

Gültig bis: 2024-01-09

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## Nitril-Handschuh

### Technische Produktspezifikation



#### Technical product specification

<b>Product name</b>	<b>semperguard sapphire blue</b>	Version / Index no:
<b>Spec code</b>	<b>NOF/NCF-030VB-N-3CZ</b>	semperguard sapphire blue_Version
<b>Date of issue</b>	<b>03.02.2020</b>	C_February 2020_EN

#### General information

<b>Type</b>	single use examination and disposable protective glove, non sterile
<b>Labelling</b>	information printed on dispenser box
<b>Shape</b>	ambidextrous - straight fingers
<b>Material</b>	Nitrile Butadiene Rubber (NBR) [not made with natural rubber latex]
<b>Colour</b>	violet blue
<b>Inside</b>	powder free
<b>Outside</b>	no treatment
<b>Cuff / surface</b>	rolled cuff / finger textured
<b>Shelf life</b>	3 years
<b>Available sizes</b>	S (6-7) M (7-8) L (8-9) XL (9-10)

#### Dimensions, physical properties and biocompatibility

<b>Glove length</b>	median $\geq$ 240 mm (according to EN 455-2)	
<b>Minimum wall thickness</b>	<i>at finger</i>	0.10 mm (double measured) / 0.05 mm (single measured)
	<i>at palm</i>	0.10 mm (double measured) / 0.05 mm (single measured)
	<i>at cuff</i>	0.08 mm (double measured) / 0.04 mm (single measured)
<b>Glove width</b>	according to EN 455-2: median S $80 \pm 10$ mm, M $95 \pm 10$ mm, L $110 \pm 10$ mm, XL $\geq 110$ mm	
<b>Force at Break</b>	median $\geq 6$ N (during shelf life according to EN 455-2)	
<b>Tensile Strength</b>	min. 14 MPa after aging (according to ASTM D6319)	
<b>Elongation at Break</b>	min. 400% after aging (according to ASTM D6319)	

**Residual powder / Powder content**  $\leq 2$  mg (according to EN 455-3)

#### Performance requirements and inspection levels

<b>Freedom from holes (Barrier)</b>	AQL $\leq 1.5$ (as per EN 455-1, sampling in accordance with ISO 2859-1, G-1)
<b>Dimensions and physical properties</b>	AQL 4.0 (as per ASTM D6319, sampling in accordance with ISO 2859-1, S-2)

#### Standards, guidelines & quality certificates

<b>Quality certification</b>	ISO 9001, ISO 13485, ISO 14001
<b>Conformity to regulations</b>	- Medical Device Regulation (EU) 2017/745: Class I - PPE Regulation (EU) 2016/425: Category III - Regulation (EC) 1935/2004 on Food Contact Materials
<b>Conformity to standards</b>	EN 420, EN ISO 374-1, EN 374-2, EN 16523-1, EN 374-4, EN ISO 374-5, EN 455-1, EN 455-2, EN 455-3, EN 455-4, ISO 2859-1, ASTM D6319, ASTM F1671

## Nitril-Handschuh

### Technische Produktspezifikation



#### Technical product specification

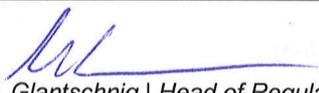
<b>Product name</b>	semperguard sapphire blue	Version / Index no:
<b>Spec code</b>	NOF/NCF-030VB-N-3CZ	semperguard sapphire blue_Version
<b>Date of issue</b>	03.02.2020	C_February 2020_EN

#### Instructions and additional statements

<b>Storage instruction</b>	Store in original packaging in a dry and dark place at 10 °C to 30 °C. Refer to guidelines of storage of rubber products as described in ISO 2230:2002. Ensure that storage area is kept cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper ions discolour the glove. Protect gloves against ultraviolet light sources, such as sunlight and oxidizing agents. Storage above 30 °C will lead to accelerated aging and should be avoided.
<b>Cautionary statement and ingredient information</b>	This product contains accelerators (Dithiocarbamate types) not to be used in a hypersensitivity of these substances. For further information, a list of substances contained in the glove is available upon request.

#### Reporting system

<b>Medical device vigilance and reporting system</b>	According to the official reporting criteria of the Medical Device Regulation, incidents caused by examination gloves must be reported immediately to our Medical Device Reporting team. E-Mail: <a href="mailto:sempermed.complaints@semperitgroup.com">sempermed.complaints@semperitgroup.com</a> or Tel.: +43 2630 310 0
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 A. Wöss Director	 J. Glantschnig   Head of Regulatory Affairs and Contract Management Sempermed	 L. Rieger Head of Product Management
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<b>Remark</b>	Replaces all previous versions. All standards references refer to the date of document issue.
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