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# Technical product specification

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

## General information

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

## Dimensions, physical properties and biocompatibility

| | | |
|---|---|---|
| **Glove length** | median ≥ 240 mm (according to EN 455-2) | |
| **Minimum wall thickness** | ***at finger*** | 0.10 mm (double measured) / 0.05 mm (single measured) |
| | ***at palm*** | 0.10 mm (double measured) / 0.05 mm (single measured) |
| | ***at cuff*** | 0.08 mm (double measured) / 0.04 mm (single measured) |
| **Glove width** | according to EN 455-2: median S 80 ± 10 mm, M 95 ± 10 mm, L 110 ± 10 mm, XL ≥ 110 mm | |
| **Force at Break** | median ≥ 6 N (during shelf life according to EN 455-2) | |
| **Tensile Strength** | min. 14 MPa after aging (according to ASTM D6319) | |
| **Elongation at Break** | min. 400% after aging (according to ASTM D6319) | |
| **Residual powder / Powder content** | ≤ 2 mg (according to EN 455-3) | |

## Performance requirements and inspection levels

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| **Freedom from holes (Barrier)** | AQL ≤ 1.5<br>(as per EN 455-1, sampling in accordance with ISO 2859-1, G-1) |
| **Dimensions and physical properties** | AQL 4.0<br>(as per ASTM D6319, sampling in accordance with ISO 2859-1, S-2) |

## Standards, guidelines & quality certificates

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| **Quality certification** | ISO 9001, ISO 13485, ISO 14001 |
| **Conformity to regulations** | - Medical Device Regulation (EU) 2017/745: Class I<br>- PPE Regulation (EU) 2016/425: Category III<br>- Regulation (EC) 1935/2004 on Food Contact Materials |
| **Conformity to standards** | 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 |

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## Instructions and additional statements

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|---|---|
| **Storage instruction** | 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. |
| **Cautionary statement and ingredient information** | 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

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| **Medical device vigilance and reporting system** | 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: sempermed.complaints@semperitgroup.com or Tel.: +43 2630 310 0 |

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|---|---|---|
| *A. Wöss*<br>*Director* | *J. Glantschnig \| Head of Regulatory Affairs and Contract Management Sempermed* | *L. Rieger*<br>*Head of Product Management* |

**Remark** Replaces all previous versions.
All standards references refer to the date of document issue.