

Technical product specification

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|---------------|-------------------|------------------------------------|
| Product name | semperguard Xpert | Version / Index no: |
| Spec code | NOT-063GB-N-3CZ | semperguard Xpert_Version February |
| Date of issue | 28/02/2019 | 2019_EN |

General information

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|-----------------|---|
| Type | single use 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 | green blue |
| Inside | powder free |
| Outside | no treatment |
| Cuff / surface | rolled cuff / textured |
| Shelf life | 3 years |
| Available sizes | S (6-7) M (7-8) L (8-9) XL (9-10) |

Dimensions, physical properties and biocompatibility

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| Glove length | median ≥ 240 mm (according to EN 455-2) |
| Minimum wall thickness | <i>at finger</i> 0.30 mm (double measured) / 0.15 mm (single measured) |
| | <i>at palm</i> 0.22 mm (double measured) / 0.11 mm (single measured) |
| | <i>at cuff</i> 0.20 mm (double measured) / 0.10 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 (as per EN 455-1, sampling in accordance with ISO 2859-1, G-1) |
| Dimensions and physical properties | AQL 4.0 (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 directives and regulations | - PPE Regulation (EU) 2016/425: III - Food Contact Materials Regulation (EC) 1935/2004 |
| Conformity to standards | EN 420, EN ISO 374-1, EN 374-2, EN 16523-1, EN 374-4, EN ISO 374-5, EN 421, EN 455 1-3, ASTM D6319, ASTM F1671 |

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Instructions and additional statements

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| Storage instruction | <p>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, as sunlight and oxidizing agents. Storage above 30 °C will lead to accelerated aging and should be avoided.</p> |
| Cautionary statement and ingredient information | <p>This product contains accelerators (Dithiocarbamate type, Zinc-mercaptobenzothiazol) not to be used in a hypersensitivity of these substances.</p> <p>For further information, a list of substances contained in the glove is available upon request.</p> |

Reporting system

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| Medical device vigilance and reporting system | Not applicable |
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|  A. Wöss <i>Director</i> |  J. Glantschnig <i>Regulatory Affairs Manager</i> <i>Sempermed</i> |  L. Rieger <i>Head of Product Management</i> |
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| Remark | <p>Replaces all previous versions.</p> <p>All standards references refer to the date of document issue.</p> |
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