

## Technical product specification

Product name	sempercure nitrile	Version / Index no:
Spec code	NOF-047OB-N-3CZ	sempercure nitrile_Version E_February
Date of issue	28/02/2019	2019_EN

### 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	ocean blue
Inside	powder free
Outside	no treatment
Cuff / surface	rolled cuff / finger textured
Shelf life	3 years
Available sizes	XS (5-6) S (6-7) M (7-8) L (8-9) XL (9-10)

### Dimensions, physical properties and biocompatibility

Glove length	median $\geq 240$ mm (according to EN 455-2)
Minimum wall thickness	<i>at finger</i> 0.20 mm (double measured) / 0.10 mm (single measured) <i>at palm</i> 0.16 mm (double measured) / 0.08 mm (single measured) <i>at cuff</i> 0.12 mm (double measured) / 0.06 mm (single measured)
Glove width	according to EN 455-2: median XS $\leq 80$ mm, S $80 \pm 10$ mm, M $95 \pm 10$ mm, L $110 \pm 10$ mm, XL $\geq 110$ mm
Force at Break	median $\geq 6$ 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	$\leq 2$ mg (according to EN 455-3)

### Performance requirements and inspection levels

Freedom from holes (Barrier)	AQL $\leq 1.5$ (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

Quality certification	ISO 9001, ISO 13485, ISO 14001
Conformity to directives and regulations	<ul style="list-style-type: none"> <li>- Medical Device Directive 93/42/EEC: Class I</li> <li>- PPE Regulation (EU) 2016/425: Category III</li> <li>- Food Contact Materials Regulation (EC) 1935/2004</li> </ul>
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 1-4, ASTM D6319, ASTM F1671

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### Instructions and additional statements

<b>Storage instruction</b>	<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>
<b>Cautionary statement and ingredient information</b>	<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

<b>Medical device vigilance and reporting system</b>	<p>According to the official reporting criteria of the Medical Device directive, incidents caused by examination gloves must be reported immediately to our Medical Device reporting officer. E-Mail: <a href="mailto:sempermed.complaints@semperitgroup.com">sempermed.complaints@semperitgroup.com</a> or Tel.: +43 2630 310 0</p>
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<b>Remark</b>	<p>Replaces all previous versions.          All standards references refer to the date of document issue.</p>
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