

## Technical product specification

<b>Product name</b>	<b>Nitrile powder free glove</b>	Version / Index no:
<b>Spec code</b>	<b>NOF/NCF-035WH-N-3CZ</b>	NOF/NCF-035WH-N-3CZ_Version
<b>Date of issue</b>	<b>07.01.2022</b>	G_January 2022_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>	white
<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>	XS (5-6) 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> 0.14 mm (double measured) / 0.07 mm (single measured) <i>at palm</i> 0.12 mm (double measured) / 0.06 mm (single measured) <i>at cuff</i> 0.10 mm (double measured) / 0.05 mm (single measured)
<b>Glove width</b>	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
<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)
<b>Residual powder / Powder content</b>	$\leq 2$ 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>	Upon request: - Medical Device Regulation (EU) 2017/745: Class I - PPE Regulation (EU) 2016/425: Category I or III - Regulation (EC) 1935/2004 on Food Contact Materials
<b>Conformity to standards</b>	EN 420 / EN ISO 21420, EN ISO 374-1 (Type B), EN 374-2, EN 16523-1, EN 374-4, EN ISO 374-5 (subject to labelling), 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

<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.</p> <p>Ensure that storage area is kept cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper ions discolour the glove.</p> <p>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.</p>
<b>Cautionary statement and ingredient information</b>	<p>This product contains accelerators (Dithiocarbamate types) 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 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</p>
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<b>Remark</b>	<p>Replaces all previous versions.</p> <p>All standards references refer to the date of document issue.</p>
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