sempermed®
A MEMBER OF THE SEMPERIT-GROUP

Technical product specification

Product name	semperguard comfort	Version / Index no:
Spec code	NOF-047OB-N-3CZ (NOF-047RB-N-3CZ)	semperguard comfort_Version F_February 2019_EN
Date of issue	28/02/2019	

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	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***	0.20 mm (double measured) / 0.10 mm (single measured)
	at palm	0.16 mm (double measured) / 0.08 mm (single measured)
	at cuff	0.12 mm (double measured) / 0.06 mm (single measured)
Glove width	according to EN 455-2: 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

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

Quality certification	ISO 9001, ISO 13485, ISO 14001
Conformity to directives and regulations	- Medical Device Directive 93/42/EEC: Class I - PPE Regulation (EU) 2016/425: Category 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 1-4, ASTM D6319, ASTM F1671

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Instructions and additional statements

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, 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 type, Zinc-mercaptobenzothiazol) 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

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

A. Wöss *Director*	*J. Glantschnig* *Regulatory Affairs Manager* *Sempermed*	*L. Rieger* *Head of Product Management*

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