sempermed®
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Technical product specification

Product name	**semperguard cobalt blue**	Version / Index no:
Spec code	**NOF-030CO-N-3CZ**	NOF-030CO-N-3CZ_Version A_January 2022_EN
Date of issue	**07.01.2022**	

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	cobalt 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 ≥ 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 XS ≤ 80 mm, 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 regulations	- 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
Conformity to standards	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

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

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

A. Wöss *Director*	f/b *M. Wachtel | Head of Quality Management and Regulatory Affairs*	*C. Rohrbach* *Head of Business Strategy*

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