

Technical product specification

Product name	sempermed latex comfort	Version / Index no:
Spec code	LCF/LOF-050NA-N-3CZ	sempermed latex comfort_LCF/LOF-050NA-N-3CZ_Version A_November 2024_EN
Date of issue	14.11.2024	

General information

Type	single use examination and disposable protective glove, non sterile
Labelling	information printed on dispenser box
Shape	ambidextrous - straight fingers
Material	Natural Rubber Latex (NRL)
Colour	natural white
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	<i>at finger</i> 0.18 mm (double measured) / 0.09 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 ≤ 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 D3578)
Elongation at Break	min. 500% after aging (according to ASTM D3578)
Residual powder / Powder content	≤ 2 mg (according to EN 455-3)

Performance requirement and inspection level

Freedom from holes (Barrier)	AQL ≤ 1.5 (as per EN 455-1, sampling in accordance with ISO 2859-1, G-1)
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Standards, guidelines & quality certificates

Quality certification	ISO 9001, ISO 13485
Conformity to regulations	- Medical Device Regulation (EU) 2017/745: Class I - PPE Regulation (EU) 2016/425: Category III - Regulation (EC) 1935/2004 on Food Contact Materials
Conformity to standards	EN ISO 21420, EN ISO 374-1 (Type C), EN ISO 374-2, EN 16523-1, EN ISO 374-4, ISO 374-5, EN 455-1, EN 455-2, EN 455-3, EN 455-4, ISO 2859-1, ASTM D3578 (except stress at 500% elongation), ASTM F1671/F1671M

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Instructions and additional statements

Storage instruction

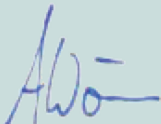
Store in original packaging in a dry and dark place at 10° C to 30° C. Refer to guidelines of storage of rubber products as described in ISO 2230:2002. Ensure that storage area is kept cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper ions discolour the glove. 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 natural rubber latex which may cause allergic reactions, including anaphylactic responses. Contains potential Type IV chemical allergens (Dithiocarbamate types, Zinc-mercaptobenzothiazol). For further information, a list of substances contained in the glove is available upon request. E-Mail: sempermed@harpsglobal.com

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@harpsglobal.com

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Remark

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