

Technical product specification

Product name	semperguard comfort	Version / Index no:
Spec code	NOF-047OB-N-3CZ	semperguard comfort_NOF-047OB-N-3CZ_Version I_May 2023_EN
Date of issue	27.04.2023	

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	5 years
Available sizes	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	<table> <tr> <td><i>at finger</i></td> <td>0.20 mm (double measured) / 0.10 mm (single measured)</td> </tr> <tr> <td><i>at palm</i></td> <td>0.16 mm (double measured) / 0.08 mm (single measured)</td> </tr> <tr> <td><i>at cuff</i></td> <td>0.12 mm (double measured) / 0.06 mm (single measured)</td> </tr> </table>	<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)
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<i>at cuff</i>	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 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, ISO 14001, ISO 45001
Conformity to regulations	<ul style="list-style-type: none"> - 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 B), EN ISO 374-2, EN 16523-1, EN ISO 374-4, ISO 374-5, EN 421, EN 455-1, EN 455-2, EN 455-3, EN 455-4, ISO 2859-1, ASTM D6319, ASTM F1671/F1671M

