

Technical product specification

Product name	semperguard Xpert	Version / Index no:
Spec code	NOT-063GB-N-3CZ	semperguard Xpert_Version February
Date of issue	28/02/2019	2019_EN

General information

Type	single use 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	green blue
Inside	powder free
Outside	no treatment
Cuff / surface	rolled cuff / 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	<i>at finger</i> 0.30 mm (double measured) / 0.15 mm (single measured)
	<i>at palm</i> 0.22 mm (double measured) / 0.11 mm (single measured)
	<i>at cuff</i> 0.20 mm (double measured) / 0.10 mm (single measured)
Glove width	according to EN 455-2: median 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	- PPE Regulation (EU) 2016/425: 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 1-3, ASTM D6319, ASTM F1671

Technical product specification

Product name	semperguard Xpert	Version / Index no:
Spec code	NOT-063GB-N-3CZ	semperguard Xpert_Version February
Date of issue	28/02/2019	2019_EN

Instructions and additional statements

Storage instruction	<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. 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.</p>
Cautionary statement and ingredient information	<p>This product contains accelerators (Dithiocarbamate type, Zinc-mercaptobenzothiazol) 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

Medical device vigilance and reporting system	Not applicable
--	----------------

 A. Wöss <i>Director</i>	 J. Glantschnig <i>Regulatory Affairs Manager</i> Sempermed	 L. Rieger <i>Head of Product Management</i>
---	---	---

Remark	<p>Replaces all previous versions.</p> <p>All standards references refer to the date of document issue.</p>
---------------	---