

Technical product specification

Product name	semperguard vinyl powder free	Version / Index no:
Spec code	VCS-048CL-N-3CZ	semperguard vinyl PF_Version
Date of issue	28/02/2019	D_February 2019_EN

General information

Type	single use disposable protective glove, non sterile
Labelling	information printed on dispenser box
Shape	ambidextrous - straight fingers
Material	Polyvinylchlorid (PVC) [not made with natural rubber latex]
Colour	transparent
Inside	polymer coated / powder free
Outside	no treatment
Cuff / surface	rolled cuff / smooth
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 ≥ 240 mm (according to EN 455-2)
Minimum wall thickness	<i>at finger</i> 0.10 mm (double measured) / 0.05 mm (single measured) <i>at palm</i> 0.14 mm (double measured) / 0.07 mm (single measured) <i>at cuff</i> 0.08 mm (double measured) / 0.04 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 ≥ 3.6 N (during shelf life according to EN 455-2)
Tensile Strength	min. 9 MPa after aging (according to ASTM D5250)
Elongation at Break	min. 300% after aging (according to ASTM D5250)
Residual powder / Powder content	≤ 2 mg (according to EN 455-2)

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 D5250, 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: Category I - Food Contact Materials Regulation (EC) 1935/2004 and (EU) 10/2011 on plastic materials
Conformity to standards	EN 420, EN 455 1-3, 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	No allergenic ingredients known. For further information, a list of substances contained in the glove is available upon request.

Reporting system

Medical device vigilance and reporting system	not applicable
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Remark	Replaces all previous versions. All standards references refer to the date of document issue.
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