

Technical product specification

Product name	sempercure vinyl powdered	Version / Index no:
Spec code	VXS-048CL-N-3CZ	sempercure vinyl PP_Version
Date of issue	28/02/2019	E_February 2019_EN

General information

Type	single use examination and 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	pre-powdered
Outside	no treatment
Cuff / surface	rolled cuff / smooth
Shelf life	5 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 \geq 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 XS \leq 80 mm, S 80 ± 10 mm, M 95 ± 10 mm, L 110 ± 10 mm, XL ≥ 110 mm
Force at Break	median \geq 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	≤ 15 mg/dm ²

Performance requirements and inspection levels

Freedom from holes (Barrier)	AQL \leq 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	<ul style="list-style-type: none"> - Medical Device Directive 93/42/EEC: Class I - 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 1-4, 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	According to the official reporting criteria of the Medical Device directive, incidents caused by examination gloves must be reported immediately to our Medical Device reporting officer. E-Mail: sempermed.complaints@semperitgroup.com or Tel.: +43 2630 310 0
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Remark	Replaces all previous versions. All standards references refer to the date of document issue.
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