

## Technical product specification

Product name	PROTECTS HYGIENIC Vinyl powderfree blue	Version / Index no:
Spec code	VCS-045RB-N-2EA	PROTECTS HYGIENIC Vinyl PF
Date of issue	28/02/2019	blue_Version C_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	regular blue
Inside	polymer coated / powder free
Outside	no treatment
Cuff / surface	rolled cuff / smooth
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	S: min. 220 mm; M-XL: min. 230 mm (according to ASTM D5250)	
Minimum wall thickness	<i>at finger</i>	0.08 mm (double measured) / 0.04 mm (single measured)
	<i>at palm</i>	0.08 mm (double measured) / 0.04 mm (single measured)
	<i>at cuff</i>	not specified
Glove width	median S 80 ± 10 mm, M 95 ± 10 mm, L 110 ± 10 mm, XL ≥ 110 mm	
Force at Break	not specified	
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 ASTM D5250)	

### Performance requirements and inspection levels

Freedom from holes (Barrier)	AQL 4.0 (sampling in accordance with ISO 2859-1, G-1 )
Dimensions and physical properties	not specified

### Standards, guidelines & quality certificates

Quality certification	ISO 9001, 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

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### Instructions and additional statements

<b>Storage instruction</b>	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.
<b>Cautionary statement and ingredient information</b>	No allergenic ingredients known. For further information, a list of substances contained in the glove is available upon request.

### Reporting system

<b>Medical device vigilance and reporting system</b>	not applicable
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 A. Wöss <i>Director</i>	 J. Glantschnig <i>Regulatory Affairs Manager</i> <i>Sempermed</i>	 L. Rieger <i>Head of Product Management</i>
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<b>Remark</b>	Replaces all previous versions. All standards references refer to the date of document issue.
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