

PRODUCT SPECIFICATION

Product name:	semperguard[®] vinyl powder free
Spec code:	VCS-048CL-N-3CZ
Date of issue:	28-Aug-2017

Type	single use disposable protective glove, non sterile	Available sizes S (6-7) M (7-8) L (8-9) XL (9-10)
Labelling	all information on dispenser box	
Shape	ambidextrous - straight fingers	
Material	Polyvinylchlorid (PVC) [not made with natural rubber latex]	
Colour	transparent	
Inner	polymer coated / powder free	
Outer	no treatment	
Cuff/surface	rolled cuff/smooth	
Storage life	5 years	

Min. thickness [in mm]	Finger	Palm	Cuff
single measured	0.045	0.065	0.040
double measured	0.09	0.13	0.08

	Before aging	After aging	Testing method
Elongation	min. 300 %	min. 300 %	ASTM D5250
Tensile strength	n.a.	n.a.	n.a.

AQL (for pinholes)	≤ 1.5	EN 374-2 EN 455-1
Residual powder / Powder content	≤ 2 mg/glove	EN 455-3
Force at break	median ≥ 3.6 N	EN 455-2
Length	median 240 mm	EN 455-2

Storage instructions

Store according to ISO 2230:2002. Ensure that the 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.

Standards, guidelines & quality certificates

Quality certification	ISO 9001 ISO 14001 OSHAS 18001
Conformity to directives	Personal Protective Equipment 89/686/EEC: Cat I for minimal risks
Conformity to standards	EN 420
	ASTM D5250
Conformity to food regulation	1935/2004 (EC) 10/2011 (EU)
	Suitable for food contact up to 2 hours at 40°C except fatty food-stuff for which food simulants D1 and D2 acc. to EC Reg. 10/2011 apply.
labelling according to	ISO 15223 EN 420

Warning and reporting system

Potentially allergenic ingredients

not known

For further information, the actual version of the ingredients list is given on request.

Medical device vigilance and reporting system

According to the official reporting criteria of MDD, incidents caused by examination gloves or surgical gloves must be reported immediately to our medical device reporting officer. E-Mail: sempermed.complaints@semperitgroup.com or Tel.: +43 2630 310 ext. -510; Fax: -549

Authorized signatory	Product management	Regulatory affairs
		
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