

PRODUCT SPECIFICATION

Product name: **semperguard® latex innercoating**
Spec code: **LCT-059NA-N-3CZ**
Date of issue: **28-Aug-2017**

Type	single use examination and 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	Natural Rubber Latex (NRL)	
Colour	natural white	
Inner	polymer coated / powder free	
Outer	no treatment	
Cuff/surface	rolled cuff/textured	
Storage life	3 years	

Min. thickness [in mm]	Finger	Palm	Cuff
single measured	0.120	0.100	0.070
double measured	0.24	0.20	0.14

	Before aging	After aging	Testing method
Elongation	min. 650 %	min. 500 %	ASTM D3578
Tensile strength	min. 18 MPa	min. 14 MPa	ASTM D3578

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 ≥ 6.0 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 13485 ISO 14001 OSHAS 18001
Conformity to directives	Personal Protective Equipment 89/686/EEC: Cat III for complex risks Medical Device Directive 93/42/EEC: Class I
Conformity to standards	EN 420 EN 455 1-4 EN 374-1-3 ASTM D3578 (except stress at 500% elongation) ASTM F1671
Conformity to food regulation	1935/2004 (EC)
labelling according to	ISO 15223 EN 420 EN 374

Warning and reporting system

Potentially allergenic ingredients

This product contains natural rubber latex which may cause allergic reactions, including anaphylactic responses.

This product contains accelerators (Dithiocarbamate type, Zinc-mercaptobenzothiazol) not to be used in a hypersensitivity of these substances.

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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