SEMPERGUARD Latex powderfree IC

PRODUCT SPECIFICATION – PRODUCT GROUP PROTECTIVE GLOVES

Product name	**SEMPERGUARD Latex powderfree IC**
Marking	all information on dispenser box
Shape	ambidextrous – single use
Material	natural rubber latex (NRL)
Internal finish	powder free coated
Colour	natural
Cuff / Surface	rolled cuff / textured

Size	**Length**	**Article number**
XS (5-6)	median 240 mm	8137 80041
S (6-7)	median 240 mm	8137 80043
M (7-8)	median 240 mm	8137 80045
L (8-9)	median 240 mm	8137 80047
XL (9-10)	median 240 mm	8137 80049

Packaging / loading volume	Dispenser box (DB) XS, S, M, L (by weight)	100	pcs
	Dispenser box (DB) XL (by weight)	90	pcs
	Transport carton (TC)	10	DB
	Container TEU	1,392	TC
	Container FEU	2,838	TC
	Container FEU High Cube	3,168	TC

Packaging dimensions:	**width** [mm]	**length** [mm]	**height** [mm]
Dispenser box	122	240	65
Transport carton	249	340	250

Thickness (double measured)	Finger: min. 0.22 mm (AQL 4.0)	Palm: min. 0.22 mm (AQL 4.0)	Cuff: min. 0.14 mm (AQL 4.0)

Storage	Protect the gloves from heat, humidity, strong light and ozone. Storing at 10°C – 30°C in a dark and dry place with 60% - 80% humidity is recommended. Date of expiry on dispenser box and transport carton.

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

Vigilance and Reporting system of MDD:
According to the official reporting criteria of MDD (Medical Device Directive) problems and reactions caused by sterile surgical gloves and similar sterile products, examination gloves (all materials) and all products made from natural latex must be reported by phone or fax within one day to the Semperit security officer (+43 2630 310 Phone 510 - Fax 549).

Potentially allergenic ingredients: (For further information the actual version of the ingredients list is given on request.)	Dithiocarbamate type
	Mercaptobenzothiazolat

pH-value:	3.5 - 9.5
Residual powder:	≤2 mg / glove

Tensile strength (before/after aging)	18 MPa / 14 MPa
Elongation (before/after aging)	650% / 500%

This product complies to regulation 1935/2004.

Quality certification	ISO 9001, ISO 13485		
Conformity to guidelines	CE Cat. III for complex risks according 89/686/EEC CE Class I for Medical Device Directive 93/42 as amended by 2007/47/EC In compliance with GMP rules (Good Manufacturing Practice)		
Type examination done by	SATRA Technology Centre (notified body 0321)		
Conformity to standards	EN 420 EN 455	EN 374-2: specified level 2 – AQL 1.5 level 3: AQL 0,65 (G1) level 2: AQL 1,5 (G1) level 1: AQL 4,0 (S4)	EN 374-3: Class 6 Sodium Hydroxide 40%

Packaging specification	latest version of Approbation SEMPERGUARD(EU)-LCI-01T

CE 0321

Customer approval:

Established (PM/DM2):	**Reviewed (QA/DM):**	**Approved (HD/DM):**
Mag. B. Schnetzlinger	DI B. Sebauer	DI C. Eichler

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