SEMPERGUARD® Nitrile Xtension

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PRODUCT SPECIFICATION – DISPOSABLE PROTECTIVE AND EXAMINATION GLOVES

Product name	**SEMPERGUARD® Nitrile Xtension**
Marking	all information on dispenser box
Shape	ambidextrous – single use
Material	nitrile rubber (NBR)
Internal finish	powder free
Colour	Blue
Cuff / Surface	rolled cuff / finger textured

Size	**Length**	**Article number**
S (6-7)	median 290 mm	8167 80863
M (7-8)	median 290 mm	8167 80865
L (8-9)	median 290 mm	8167 80867
XL (9-10)	median 290 mm	8167 80869

Packaging / loading volume	Dispenser box (DB) S, M, L (by weight)	100	pcs
	Dispenser box (DB) XL (by weight)	90	pcs
	Transport carton (TC)	10	DB
	Container TEU	1.078	TC
	Container FEU	2.156	TC
	Container FEU High Cube	2.429	TC

Packaging dimensions:	**width** [mm]	**length** [mm]	**height** [mm]
Dispenser box	125	275	74
Transport carton	260	360	290

Thickness (double measured)	Finger: min. 0.18 mm (AQL 4.0)	Palm: min. 0.16 mm (AQL 4.0)	Cuff: min. 0.10 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 (3 years) on dispenser box and transport carton.

Caution! This product contains accelerators which may cause allergic reactions!

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

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

Tensile strength (before/after aging)	18 MPa / 14 MPa
Elongation (before/after aging)	500% / 400%

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)NOIC_XT_3F

CE 0321

Customer approval:

Established (PM/DM2):	**Reviewed (QM/DM):**	**Approved (HD/DM):**
Mag. M. Schirmbrandt	DI B. Sebauer	DI C. Eichler

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