

Sempercare® Edition IC

PRODUCT SPECIFICATION

Product name	Sempercare® Edition IC
Type	Single-use disposable examination and protective glove
Marking	all information on dispenser box
Shape	straight fingers, ambidextrous
Material	Natural Rubber Latex (NR), powder-free
Colour	natural white
Cuff / Surface	rolled rim / extra rough surface

Size	Length [according to EN 455-2]	Width [according to EN 455-2]
XS (5-6)	med. 240 mm	med. ≤80
S (6-7)	med. 240 mm	med. 80 ± 10
M (7-8)	med. 240 mm	med. 95 ± 10
L (8-9)	med. 240 mm	med. 110 ± 10
XL (9-10)	med. 240 mm	med. ≥110

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

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

Thickness (double measured)	Palm: min. 0.16 mm (AQL 4.0)
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Residual powder [according to EN 455-3]	≤2 mg / glove
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This product complies to regulation 1935/2004 [contact with food]	
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Force at break [according to EN 455-2]	med. 6,0 N (during shelf life) / med. 6,0 N (after challenge testing)
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Quality certification	ISO 9001, ISO 13485		
Conformity to guidelines	Medical Device Directive 93/42/EEC: CE Class I Personal Protective Equipment 89/686/EEC: CE cat. III In compliance with GMP rules (Good Manufacturing Practice)		
Type examination done by	SATRA Technology Centre (notified body 0321)		
Conformity to standards	EN 455 EN 420	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 H ydroxide 40%

Storage	3 years storage life (date of expiration see on the box). Keep area 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.
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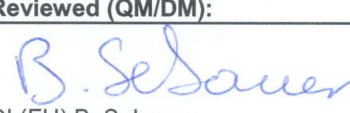
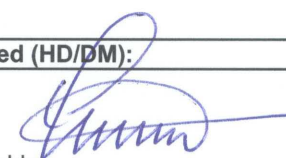
Caution! This product contains natural rubber latex which may cause allergic reactions including anaphylactic reactions!
This product contains accelerators which may cause allergic reactions!

Potentially allergenic ingredients: (For further information the actual version of the ingredients list is given on request.)	Dithiocarbamate type Zinc-Mercaptobenzothiazolate
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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. Tel: +43 2630 310 ext. -510; Fax -549



Customer approval:

Established (PM/DM1):  G. Dohr	Reviewed (QM/DM):  DI (FH) B. Sebauer	Approved (HD/DM):  DI C. Eichler
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