

GLOVE SPECIFICATION



GENERAL INFORMATION

Type:	single-use disposable examination or protective glove
Marking:	all information on dispenser box
Shape:	ambidextrous – straight fingers
Material:	Polyvinylchlorid (PVC)
Colour:	clear
Inner:	polymer coated
Outer:	no treatment
Cuff/Surface:	rolled cuff/smooth

Thickness: <small>(double measured)</small>	Finger: min. 0.09 mm	Palm: min. 0.13 mm	Cuff: min. 0.08 mm
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Residual powder: <small>(according to EN 455-3)</small>	≤ 2 mg / glove
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Force at break: <small>(according to EN 455-2)</small>	med. 3.6 N <small>(during shelf life)</small>
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Length: <small>(according to EN 455-2)</small>	median 240 mm
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Available Sizes:	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)
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Storage: 5 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.

STANDARDS, GUIDELINES AND QUALITY CERTIFICATION

Quality certification:	ISO 9001, ISO 13485
Conformity to guidelines:	Personal Protective Equipment 89/686/EEC Cat I Medical Device Directive 93/42/EEC: Class I (subject to declaration of brand owner)

Conformity to standards:	EN 420	EN 374-2: specified
	EN 455	level 2 - AQL 1.5
	ASTM D5250	level 3: AQL <0.65 (G1) level 2: AQL <1.5 (G1) level 1: AQL <4.0 (S4)

Conformity to food regulation: 1935/2004 
Vinyl gloves are not suitable for handling fatty food!

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. Tel.: +43 2630 310 ext. -510; Fax: -549