

# TECHNICAL DATA SHEET

**Reference:** Fusione  
**Article No.:** 1200000, 1200001, 1200002, 1200003, 1200004, 1200005, 1200006, 1200007  
**Description:** Polyisoprene Surgical glove, sterile, powder-free, natural, category III, class IIa  
**Usage:** For single use in the medical sector.



## CHARACTERISTICS

All sizes:	Thickness (single wall)							
	<u>Length*</u>	<u>Cuff</u>	<u>Palm</u>			<u>Finger</u>		
	min. 295mm	0,17±0,02mm	0,19±0,02mm			0,22±0,02mm		
Palm width:	<u>5,5</u>	<u>6,0</u>	<u>6,5</u>	<u>7,0</u>	<u>7,5</u>	<u>8,0</u>	<u>8,5</u>	<u>9,0</u>
	72±0,05mm	77±0,05mm	83±0,05mm	89±0,05mm	95±0,05mm	102±0,05mm	108±0,05mm	114±0,05mm

*\*in accordance to EN 455-2*

## DESIGN

Material:	polyisoprene	Color:	natural
Powder:	powder-free	External surface:	textured
Powder content**:	max. 2 mg per glove	Shape:	handspecific
Protein content:	n/d	Cuff:	beaded cuff
Internal surface:	polymer-coated	Sterilization:	sterile (Gamma rays or electron beams)

*\*\*in accordance to ASTM D-6124*

## PHYSICAL PROPERTIES

	<u>Before Aging</u>		<u>After Aging</u>
Force at break:	min. 9 N	Force at break:	min. 9 N
AQL:	0,65		

## LOGISTIC DATA

	<u>Pouch</u>	<u>Dispenser</u>	<u>Outer carton</u>
Quantities:	1 pair	50 pair of gloves	4 x 50 pair of gloves
Dimensions (LxWxH):	25,3 x 13 cm	25 x 12,9 x 22,5 cm	50,8 x 13,6 x 45,8 cm
Shelf life:	5 years		
Storage:	Store in original packaging in a dry and dark place at room temperature. Protect from heat, humidity, bright light and ozone.		

## LABELLING

Batch number:	Depending on the version
Manufacturing date:	Depending on the version
Expiry date:	Depending on the version

## QUALITY MANAGEMENT

Product-related standards:	EN ISO 374-1:2016+A1:2018 / Type B   EN 374-2:2019   EN 374-4:2019   EN 374-5:2016     EN 16523-1:2015+A1:2018   EN ISO 21420:2020   EN 421:2010     EN 455-1:2020   EN 455-2:2015   EN 455-3:2015   EN 455-4:2009     ISO 11137-2:2015
Quality certificates:	ISO 13485:2016

Medical Device: Medical device, class IIa, in accordance to directive 93/42/EEC including its additions and amendments by Directive 2007/47/EEC

Personal Protective Equipment: Personal protective equipment in accordance to Regulation (EU) 2016/425 CE Category III: For irreversible or mortal risks



EN ISO 374-1:2016/Type B



EN ISO 374-5:2016



EN 421:2010



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#### DISPOSAL

Dispose in accordance with the valid regulations. Gloves contaminated with chemical substances must be disposed of in accordance with the regulations for the relevant chemicals.

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#### NOTICES

**Usage:** The product needs to be checked for the correct size and suitability with regard to its intended use. Before use check for damage and do not use damaged or unsuitable gloves. The gloves are intended for single use only and shall be disposed on a regular basis.

**Caution:** The product may cause allergic reactions on sensitive people. Particular caution must be exercised if the user has any known or suspected hypersensitivity.

The information above are to be considered as typical values in the standard version based on the manufacturer's information. Subject to modification.

The gloves shall only be used for its intended purpose. If needed we're glad to support you with further details.

#### Technical data sheet issued by

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(Signature and company stamp)

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