ulma International GmbH
Alfred-Nobel-Str. 5
50226 Frechen
Deutschland / Germany

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

		Thickness (single wall)		
	Length*	Cuff	Palm	Finger
All sizes:	min. 295mm	0,17±0,02mm	0,19±0,02mm	0,22±0,02mm

	6,0	6,5	7,0	7,5	8,0	8,5	9,0
Palm width:	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 // *** in accordance to ASTM D-5712*

PHYSICAL PROPERTIES

	Before Aging		After Aging
Force at break:	min. 9 N	Force at break:	min. 9 N
AQL:	0,65		

LOGISTIC DATA

	Pouch	Dispenser	Outer carton
Quantities:	1 set	50 sets of gloves	4 x 50 sets of surgical 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

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Medical Device:	Medical device, class IIa, in accordance to Regulation 2017/745
Personal Protective Equipment:	Personal protective equipment in accordance to Regulation (EU) 2016/425 CE Category III: For irreversible or mortal risks

CE 2777 EN ISO 374-1:2016/Type B KPT EN ISO 374-5:2016 VIRUS EN 421:2010

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.

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 typicial 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

ulma International GmbH
Alfred-Nobel-Str. 5
50226 Frechen
Deutschland / Germany

ulma
Alfred-Nobel-Str. 5
50226 Frechen
info@ulma.de

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(Signature and company stamp)

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