
		Technical Data Sheet	
Peha-taft® LATEX		Spec.-No.:	D 6.5585
		Department:	CEO-DOE
		Date:	2019-05-01

1. General Product Description

- powderfree surgical gloves, for single use; sterile; made of thin and soft natural rubber latex; with polymer coating
- medical product class IIa
- personal protective equipment category III
- double-gloving
- good tactile sensitivity, optimised grip, micro rough surface; highly elastic and tear resistant; full anatomic shape

Peha-taft® LATEX is classified as a class II a medical device and as category III personal protective equipment. A conformity assessment has been performed for Peha-taft® LATEX and it has been shown to be in compliance with all requirements of the applicable directives and regulations of the European Union.

The safe use and effectiveness Peha-taft® LATEX is therefore ensured, if the product is used in line with the intended purpose.

2. Application / Indication

In general, surgical gloves are single-use products for usage in all kinds of surgical procedures.

Surgical gloves are single-use sterile surgical gloves for short-term prevention of infections, germ transmission, and cross contamination during medicinal procedures/interventions in clinical and home environment. Surgical gloves can be applied (optional) in combination with a second pair of operation gloves as an underglove.

Additional intended use as personal protective equipment. Protective gloves provide limited protection against hazardous substances.

3. Presentation (packaging)

- sterile
 - with turned up cuff
 - packed in pairs in inner wrapping paper and sealed in easy to open peel pouch
 - colour code of the packaging: green
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- transport carton dimension: 48.0 cm x 28.3 cm x 45.0 cm (L x W x H)
 - dispenser dimension: 27.0 cm x 15.0 cm x 22.0 cm (L x W x H)

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size	reference number	dispenser	transport carton
5.5	942 589/3	50 pairs	6
6.0	942 590/3	50 pairs	6
6.5	942 591/3	50 pairs	6
7.0	942 592/3	50 pairs	6
7.5	942 593/3	50 pairs	6
8.0	942 594/3	50 pairs	6
8.5	942 595/3	50 pairs	6
9.0	942 596/3	50 pairs	6

4. Product Characteristics

material composition:

- material: modified natural rubber (produced from natural latex) with interior polymer coating
- accelerators: type of carbamates
free of thiurames and mercaptobenzothiazoles
- antioxidants: phenolic derivate
- water-soluble proteins : recent test results:



EN 455 requirement	average values
< 50 µg/g	Modified Lowry <30 µg/g HPLC Method < 30 µg/g

→ If required, HARTMANN certainly helps with further details.

Product design:

- colour: latex-white to yellow
- surface structure: micro rough
- interior coating: polymer
- form: full anatomic
- cuff: beaded
- overall length and overall width (according to EN 455-2):

size	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
length: mm (min.)	270	270	270	280	280	280	285	285
width: mm	70 – 76	76 – 82	82 – 88	88 – 94	94 – 100	102 – 108	108 – 114	109 – 115

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- film thickness (average values):

	cuff	palm	finger tip
Single wall thickness	min. 0.16 mm	min. 0.16 mm	min. 0.20 mm
Double wall thickness	min. 0.32 mm	min. 0.32 mm	min. 0.40 mm

material characteristics:

tear strength/force at break:		
	standard requirement (EN 455-2)	average values for Peha-taft® LATEX
Throughout shelf life and within 12 months of manufacture after challenge testing	≥ 9.0 N	17 N

→ recent test results available on request


5. Product Requirements


The gloves comply with the essential requirements as medical devices and the standards:



EN 455-1:	Requirements and testing for freedom of holes (AQL ≤ 1.5) The HARTMANN minimum request is AQL ≤ 0.65
EN 455-2:	Requirements and testing for physical properties
EN 455-3:	Requirements and testing for biological evaluation
EN 455-4:	Requirements and testing for shelf life determination
EN 420:	Protective gloves- General requirements and test methods
EN ISO 374-1:	Terminology and performance requirements for chemical risks
EN 374-2:	Determination of material resistance to penetration
EN 16523-1:	Determination of material resistance to permeation by chemicals
EN 374-4:	Determination of material resistance to degradation by chemicals
EN ISO 374-5:	Terminology and performance requirements for micro-organisms risks
ASTM F1671 / ISO 16604:	Resistance to Virus Penetration
EN 421:	Protective gloves against ionizing radiation and radioactive contamination (radioactive contamination protection only)

→ recent test results available on request

6. Labelling

Lot-No. with 9-digit code: e.g.  8 XXX XX XX X
year internal key

manufacturing date: e. g.  2014 01
year month

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expiry date: e.g.  2019 02
year month

shelf life: 5 years

7. Packaging

Peha-taft® LATEX gloves are sealed in pairs and available in dispenser boxes; 6 dispenser boxes are packaged in one transport carton; sealed with adhesive tapes; packed on euro-pallets.

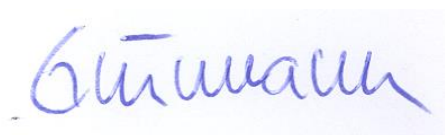
8. Sterilisation

Gamma-sterilisation according to DIN EN ISO 11137 and EN 556; min. 25 kGy.

Date: 2019-05-01

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