
		Technical Data Sheet	
Peha-taft® classic POWDERFREE		Spec.-No.:	D 6.5550
		Department:	CEO-DOE
		Date:	2019-05-01

1. General Product Description

- powderfree surgical glove, for single use; made of thin and soft natural rubber latex
- medical device class II a
- personal protective equipment category III
- micro smooth surface for good tactile sensitivity; highly elastic and tear resistant; full anatomic shape

Peha-taft® classic POWDERFREE 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® classic POWDERFREE 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 of Peha-taft® classic POWDERFREE 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 wrapping paper and sealed in easy to open peel pouch
- colour code of the packaging: light blue
- transport carton dimension: 52.7 cm x 25.7 cm x 23.3 cm (L x W x H)
- dispenser dimension: 25.0 cm x 12.9 cm x 22.5 cm (L x W x H)

size	reference number	dispenser	transport carton
5.5	942 644/5	50 pairs	4
6.0	942 645/5	50 pairs	4
6.5	942 646/5	50 pairs	4
7.0	942 647/5	50 pairs	4
7.5	942 648/5	50 pairs	4
8.0	942 649/5	50 pairs	4
8.5	942 650/5	50 pairs	4
9.0	942 651/5	50 pairs	4

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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 derivative
- 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 smooth
- 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.)	295	295	295	295	295	295	295	295
width: mm	72 ± 4	77 ± 5	83 ± 5	89 ± 5	95 ± 5	102 ± 6	108 ± 6	114 ± 6

- film thickness (average values):

	cuff	palm	finger tip
Single wall thickness	0.18 mm	0.20 mm	0.22 mm
Double wall thickness	0.36 mm	0.40 mm	0.44 mm

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material characteristics:

tear strength/force at break:		
	standard requirement (EN 455-2)	average values for Peha-taft® classic POWDERFREE
Throughout shelf life and within 12 months of manufacture after challenge testing	≥ 9.0 N	16 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 of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System (viral 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
expiry date:	e.g.		2019	02
			year	month
shelf life:	5 years			

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7. Packaging

Peha-taft® classic POWDERFREE gloves are sealed in pairs and available in dispenser boxes; 4 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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i. A.



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