

Peha-taft® classic	and the second sec	SpecNo.:	D 6.5551
powdered, Latex	and The	Department:	CMO-DOE
sterile	- S	Date:	2015-01-01

# 1. General Product Description

- powdered surgical glove, for single use; sterile; made of thin and extra-soft natural rubber latex
- medical product class II a
- personal protective equipment class III
- textured fingers for optimised textile sensitivity and grip
- highly elastic and tear resistant; high wearing comfort; no tiring of fingers due to full anatomic shape

Peha-taft<sup>®</sup> classic, sterile, carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class II a medical device.

Peha-taft<sup>®</sup> classic, sterile, carries the CE mark according to EU directive 89/686/EEC for Personal Protective Equipment. The product is classified as category III personal protection equipment. A conformity assessment has been performed for Peha-taft® classic, sterile, and it has been shown to be in compliance with all applicable requirements of the above mentioned directives. The safe use and effectiveness Peha-taft® classic, sterile, therefore, is ensured if the product is used in line with the intended purpose.

# 2. Application / Indication

Universally usable in all types of surgery and additionally qualified as personal protective equipment and therefore applicable in laboratories, when handling with chemicals or cytostatica.

# 3. Presentation (packaging)

- sterile
- with turned up cuff
- packed in pairs in wrapping paper and sealed in easy to open peelpouch
- packaging material: latex-free
- colour code of the packaging: dark 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	942 740/3	50 pairs	4
6.0	942 741/3	50 pairs	4
6.5	942 742/3	50 pairs	4
7.0	942 743/3	50 pairs	4
7.5	942 744/3	50 pairs	4
8.0	942 745/3	50 pairs	4
8.5	942 746/3	50 pairs	4
9.0	942 747/3	50 pairs	4

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### 4. Product Characteristics

#### material composition:

- material: modified natural rubber
- powder:
- accelerators:
- antioxidants:
- water-soluble Protein:

absorbable corn starch (USP) type of Carbamates free of Thiurames and Mercaptobenzothiazoles phenolic derivative < 80 µg/g recent test results:

EN 455 requirement	average values
< 80 µg/g	Modified Lowry < 80 µg/g
	HPLC Method < 80 µg/g

 $\rightarrow$  If required, HARTMANN certainly helps with further details.

#### product design:

- colour:
- surface structure:
- latex-white to yellow
- textured medium
- grip strength: powdered
- interior coating: • form:
- cuff:
- full anatomic 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.)	280	280	280	280	280	280	280	280
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	0.21 mm
Double wall thickness	0.36 mm	0.40 mm	0.42 mm

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material characteristics:

tear strength/force at break:		
	norm requirement (EN 455-2)	average values for Peha-taft classic powdered, sterile
Throughout shelf life and within 12 months of manufacture after challenge testing	≥ 9.0 N	14 N

 $\rightarrow$  recent test results available on request

#### 5. Product Requirements

The gloves comply with the essential requirements of the Council Directive 93/42/EEC for medical products and the standards.

EN 455-1:	Requirements and testing for freedom of holes (AQL $\leq$ 1.5) The HARTMANN minimum request is AQL $\leq$ 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 388	Protective gloves against mechanical risks
EN 374	Protective gloves against chemicals and micro-organisms
ASTM F1671	Resistance to Virus Penetration

 $\rightarrow$  recent test results available on request

# 6. Labelling

Lot-No. with 9-digit code:	e.g.	8 year	XXX XX XX X internal key
manufacturing date:	e. g.	year	2014 01 month
expiry date:	e.g.	X	2019 02 year month
shelf life:	5 yea	rs	

HARTMANN	Technical Data Sheet
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#### 7. Packaging

sterile

Peha-taft<sup>®</sup> classic, sterile, gloves are sealed in pairs and available in dispenser boxes; 4 dispenser boxes are packaged in one transport carton acc. DIN; sealed with adhesive tapes.

Date:

2015-01-01

#### 8. <u>Sterilisation</u>

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

Date: 2015-01-01

PAUL HARTMANN AG CMO- Development OTM & Exam. Gloves (CMO-DOE)

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Eugen Grummann