


<b>Peha-taft® classic powder-free, Latex sterile</b>		Spec.-No.:	D 6.5550
		Department:	CMO-DOE
		Date:	2015-01-01

### 1. General Product Description

- powder-free surgical glove, for single use; made of thin and extra-soft natural rubber latex
- medical product class II a
- personal protective equipment class III
- micro rough surface and medium grip level for good touch sensitivity
- highly elastic and tear resistant; high wearing comfort; no tiring of fingers due to full anatomic shape

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Peha-taft® classic powder-free, 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® classic powder-free, 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 Peha-taft® classic powder-free, 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 powder-free, 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: 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	942 644/4	50 pairs	4
6.0	942 645/4	50 pairs	4
6.5	942 646/4	50 pairs	4
7.0	942 647/4	50 pairs	4
7.5	942 648/4	50 pairs	4
8.0	942 649/4	50 pairs	4
8.5	942 650/4	50 pairs	4
9.0	942 651/4	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: < 30 µg/g  
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
- grip strength: medium
- 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:**

<b>tear strength/force at break:</b>		
	norm requirement (EN 455-2)	average values for Peha-taft classic powder-free, sterile
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 of the Council Directive 93/42/EEC for medical products 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 388	Protective gloves against mechanical risks
EN 374	Protective gloves against chemicals and micro-organisms
ASTM F1671	Resistance to Virus Penetration

→ 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   02  
    year    month

expiry date:                              e.g.    ⌚    2019   01  
    year    month

shelf life:                                        5 years

		<h1>Technical Data Sheet</h1>
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		Depart-ment:	<b>CMO-DOE</b>
		Date:	<b>2015-01-01</b>

7. Packaging

Peha-taft® classic powder-free, 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; packaged on euro-pallets.

8. Sterilisation

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)

i. A.



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