



Peha-taft® classic
powdered, Latex
sterile



Spec.-No.:	D 6.5551
Department:	CMO-DOE
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® 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® 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

Peha-taft® classic powdered, Latex sterile		Spec.-No.:	D 6.5551
		Department:	CMO-DOE
		Date:	2015-01-01

4. Product Characteristics

material composition:

- material: modified natural rubber
- powder: absorbable corn starch (USP)
- accelerators: type of Carbamates
free of Thiurames and Mercaptobenzothiazoles
- antioxidants: phenolic derivative
- water-soluble Protein: < 80 µg/g
recent test results:

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

→ If required, HARTMANN certainly helps with further details.

product design:

- colour: latex-white to yellow
- surface structure: textured
- grip strength: medium
- interior coating: powdered
- 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.)	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

		<h1>Technical Data Sheet</h1>
--	--	-------------------------------

Peha-taft® classic powdered, Latex sterile		Spec.-No.:	D 6.5551
		Department:	CMO-DOE
		Date:	2015-01-01

7. Packaging

Peha-taft® 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.

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.



Eugen Grumann