



**Peha-micron<sup>®</sup> plus**  
**powder-free, Latex**  
**sterile**



Spec.-No.:	D 6.5566
Department:	CMO-DOE
Date:	2013-07-26

### 1. General Product Description

- powder-free surgical gloves, for single use; sterile; made of ultra-thin and extra-soft natural rubber latex; with polymer coating
- medical product class II a
- ultra-thin for extra-ordinary good touch sensitivity
- enforced cuff
- brown coloured, avoids light reflection
- optimised grip; highly elastic and tear resistant; no tiring of fingers due to full anatomic shape

Peha-micron<sup>®</sup> plus, 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.

A conformity assessment has been performed for Peha-micron<sup>®</sup> plus, powder-free, sterile and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of Peha-micron<sup>®</sup> plus, 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; especially for microsurgery and vascular surgery ; also usable as underglove.

### 3. Presentations (packaging)

- sterile
- with rolled edge
- packed in pairs in inner wrapping paper and sealed in easy to open PE-peelpouch
- packaging materials: latex-free
- colour code of the packaging: brown
- transport carton dimension: 59.0 cm x 31.5 cm x 23.5 cm (L x W x H)
- dispenser dimension: 29.0 cm x 15.0 cm x 22.5 cm (L x W x H)

size	reference number	dispenser	transport carton
6.0	942 571/2	50 pairs	4
6.5	942 572/2	50 pairs	4
7.0	942 573/2	50 pairs	4
7.5	942 574/2	50 pairs	4
8.0	942 575/2	50 pairs	4
8.5	942 576/2	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 und Mercaptobenzothiazoles
- antioxidants: phenolic derivative
- water-soluble proteins: according to EN 455 < 50 µg/g  
recent test results (Modified Lowry, HPLC-Method) on request

→ If required, HARTMANN certainly helps with further details.

##### product design:

- colour: brown
- surface structure: smooth (non-textured)
- grip strength: medium
- interior coating: polymer
- form: full anatomic
- cuff: beaded
- overall length and overall width (according to EN 455-2):

size	6.0	6.5	7.0	7.5	8.0	8.5
length: mm (min.)	280	280	283	294	295	297
width: mm	72 – 82	78 – 88	84 – 94	90 – 100	96 – 108	102 - 114

- film thickness (average values):

cuff	palm	finger tip
0.15 mm	0.15 mm	0.17 mm



		<h1>Technical Data Sheet</h1>
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7. Packaging

Peha-micron<sup>®</sup> plus 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 EN 552; min. 25 kGy

Date: 2013-07-26

PAUL HARTMANN AG  
 CMO-DOE Development OTM & Exam Gloves

i. A.



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