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|----------------------------------------------------|------------------------------------------------------------------------------------|-------------|------------|
| Peha-soft® powder-free, Latex sterile |  | Spec.-No.: | D 9.5202 |
| | | Department: | CMO-DOE |
| | | Date: | 2013-08-01 |

1. General Product Description

- powder-free examination gloves, for single use; sterile; made of thin and extra-soft latex
- medical product class I
- textured fingers for extra good touch sensitivity and safe grip
- excellent fit and wearing comfort

Peha-soft® powder-free, sterile carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class I medical device. A conformity assessment has been performed for Peha-soft® powder-free, sterile and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use and effectiveness of Peha-soft® powder-free, sterile, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

For changing dressings, minor surgery, catheterisations, biopsies etc.

3. Presentation (packaging)

- sterile
 - packed in pairs in wrapping paper and sealed in paper peelpouch
 - packaging material: latex-free
 - colour code of the packaging: light blue
- transport carton dimension: 52.5 cm x 30.5 cm x 23.0 cm (L x W x H)
 - dispenser dimension: 26.0 cm x 15.0 cm x 22.0 cm (L x W x H)

| size | reference number | dispenser | transport carton |
|------------------|------------------|-----------|------------------|
| S (6.5 – 7.0) | 942 770/4 | 50 pairs | 4 |
| M (7.5 – 8.0) | 942 771/4 | 50 pairs | 4 |
| L (8.5 – 9.0) | 942 772/4 | 50 pairs | 4 |

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4. Product Characteristics

material composition:

- material: modified natural rubber*
(*produced from natural latex)
- accelerators: type of carbamates
free of Thiurames and Mercaptobenzothiazoles
- antioxidants: phenolic derivative
- water-soluble proteins: according to EN 455 < 50 µg/g
recent test results

| EN 455 requirement | average values |
|--------------------|---------------------------------------------------|
| < 50 µg/g | Modified Lowry 10.7 µg/g HPLC Method 15.7 µg/g |

→ If required, HARTMANN certainly helps with further details.

product design:


- colour: yellowish
- surface structure: textured fingers
- grip strength: low
- interior coating: chlorinated
- form: to be worn left or right
- cuff: beaded

- overall length and overall width (according to EN 455-2):

| size | S | M | L |
|----------------------|---------|---------|----------|
| length: mm (min.) | 240 | 240 | 240 |
| width: mm | 80 ± 10 | 95 ± 10 | 110 ± 10 |

- film thickness (average values):

| cuff | palm | finger tip |
|---------|---------|------------|
| 0.13 mm | 0.15 mm | 0.19 mm |

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|  HARTMANN | <h1>Technical Data Sheet</h1> |
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material characteristics:

| tear strength/force at break: | | |
|--------------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------|
| | norm requirement (EN 455-2) | average values for Peha-soft powder-free, sterile |
| Throughout shelf life and within 12 months of manufacture after challenge testing | ≥ 6.0 N | 8 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) |
| 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 |

→ 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.  2008 06
 year month

expiry date: e.g.  2011 06
 year month

shelf life: 3 years

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7. Packaging

Peha-soft®, 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 europallets.

8. Sterilisation

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

Date: 2013-08-01

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

i. A.



Eugen Grumann