

Peha®-neon plus
powder-free, latex-free (Polychloroprene)
sterile



Spec.-No.: D 6.5565

Department: SM-PDO

Date: 2011-07-01

1. General Product Description

- powder-free synthetic surgical gloves, for single use; sterile; made of synthetic Polychloroprene; with polymer coating
- medical product class II a
- excludes allergies against latex proteins (allergy type I)
- highly elastic material, therefore good fit and wearing comfort
- very good touch sensitivity due to textured surface; no tiring of fingers due to full anatomic shape
- free of carbamats, mercaptobenzothiazols and thiurames (accelerators); therefore reduced risk of type IV allergy

Peha®-neon 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®-neon 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 and effectiveness of Peha®-neon 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 users and patients with allergy against latex proteins (allergy type I). Free of carbamates, mercaptobenzothiazoles and thiurames; therefore often usage of Peha®-neon plus possible for users or patients suffering of allergy type IV against accelerators mentioned above.

3. Presentation (packaging)

- sterile
- with turned up cuff
- packed in pairs in inner wrapping paper and sealed in easy to open PE-peelpouch
- packaging material: latex-free
- colour code of the packaging: orange
- transport carton dimension: 32.0 cm x 30.0 cm x 29.0 cm (L x W x H)
- dispenser dimension: 29.0 cm x 15.0 cm x 14.0 cm (L x W x H)

size	reference number	dispenser	transport carton
6.0	942 545/1	25 pairs	4
6.5	942 546/1	25 pairs	4
7.0	942 547/1	25 pairs	4
7.5	942 548/1	25 pairs	4
8.0	942 549/1	25 pairs	4
8.5	942 550/1	25 pairs	4

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emergency set:



size	reference number	dispenser	transport carton
5 sizes à 2 pairs (6.5 – 8.5)	942 639/6	10 pairs	6

4. Product Characteristics

material composition:

- material: Polychloroprene with interior polymer coating
- antioxidants: phenolic derivative
- accelerators: type of guanidine (DPG) and type of thiourea (DPTU)
free of carbamates, thiurames and mercaptobenzothiazoles (MBT)

→ If required, HARTMANN certainly helps with further details.

product design:

- colour: brown
- surface structure: palm of hand: textured, back of hand: smooth
- 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.)	295	295	295	295	295	295
width: mm	73 – 81	79 – 87	85 – 93	90 – 100	97 – 107	103 – 113

- film thickness (average values):

cuff	palm	finger tip
0.16 mm	0.19 mm	0.21 mm

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material characteristics:

tear strength / force at break		
	Norm requirement (EN 455-2)	average values for Peha-neon plus powder-free, sterile
Throughout shelf life and within 12 months of manufacture after challenge testing	≥ 9,0 N	11,0 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 ≤1.0
- 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. 1 XXX XX XX X
 year internal key

manufacturing date: e. g.  2011 06
 year month

expiry date: e.g.  2016 06
 year month

shelf life: 5 years

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7. Packaging

Peha®-neon 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 DIN EN ISO 11137 + EN 556; min. 25 kGy.

Date: 2011-07-01

PAUL HARTMANN AG
- SM-PDO Solution Management
- Product Development OR-Management

i. A.



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