
		Technical Data Sheet	
Peha-soft® powder-free, Latex non-sterile		Spec.-No.:	D 9.5203
		Department:	CMO-DOE
		Date:	01.09.2015

1. General Product Description

- double chlorinated, powder-free examination glove, for single use; non-sterile; made of thin and extra-soft latex
- medical product class I
- approved for food contact
- textured fingers for extra good touch sensitivity and safe grip
- excellent donning properties, fit and wearing comfort
- to be worn left or right

Peha-soft® powder-free 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 and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of Peha-soft® powder-free, therefore, is ensured if the product is used in line with the intended purpose.


2. Application / Indication

For universal use in the medical field, where high wearing comfort and excellent sensitivity is requested. In addition approved for contact with food (kitchen).

3. Presentation (packaging)

- non-sterile
- to be taken out of dispenser by piece
- packaging materials: latex-free
- colour code of the packaging: light blue
- transport carton dimension: 38.9 cm x 24.9 cm x 26.6 cm (L x W x H)
- dispenser dimension: 24.0 cm x 12.5 cm x 7.5 cm (L x W x H)

size	reference number	dispenser	transport carton
XS	942 159/5	100 pieces	10
S	942 160/5	100 pieces	10
M	942 161/5	100 pieces	10
L	942 162/5	100 pieces	10
XL	942 163/5	100 pieces	10

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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

→ If required, HARTMANN certainly helps with further details.

product design:

- colour: yellowish
- surface structure: textured fingers
- grip strength: low
- interior coating: chlorinated
- exterior coating: chlorinated
- form: to be worn left or right
- cuff: beaded
- overall length and overall width (according to EN 455-2):

size	XS	S	M	L	XL
length: mm (min.)	240	240	240	240	240
width: mm	≤ 80	80 ± 10	95 ± 10	110 ± 10	≥ 110

- film thickness (average values):

cuff	palm	finger tip
0.10 mm	0.15 mm	0.19 mm

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material characteristics:

tear strength/force at break:	EN 455-2 requirement	average values for Peha-soft powder-free, non-sterile
throughout shelf life and within 12 months of manufacture after challenge testing	≥ 6 N	10,0 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)
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


aqueous extractable proteins	EN 455-3 requirement	average values for Peha-soft powder-free, non-sterile
modified Lowry method and Amino acid analysis (AAA) by HPLC	< 50 µg/g	< 30 µg/g


→ recent test results available on request

additional qualification: approved for food contact



6. Labelling

Lot-No. with 9-digit code: e.g. 1 XXX XX XX X
year internal key

manufacturing date: e.g.  2012 06
year month

expiry date: e.g.:  2015 06
year month

shelf life: 3 years

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7. Packaging

Peha-soft® powder-free gloves are available in dispenser boxes; dispenser boxes are packaged in transport cartons acc. DIN; sealed with adhesive tapes; packaged on europallets.

Date: 2015-09-01

PAUL HARTMANN AG
CMO-Development OTM & Exam. Gloves (CMO-DOE)
CMO-Development Packaging Medical Supply (CMO-DPM)

i. A.



Dr. Siegfried Kumpf