

Peha-soft® syntex powder-free, latex-free (Stretch-Vinyl) non-sterile



SpecNo.:	D 8.0002
Department:	CMO-DOE
Date:	2013-12-12

1. General Product Description

- powder-free examination glove, for single use; non-sterile; made of synthetic stretch-vinyl, elastic
- medical product class I
- visually comparable to a latex glove due to colour
- · elastic, tear resistant and safe
- excellent fit and tactile sensitivity
- to be worn left or right
- free of allergy risk type I (against latex proteins) and type IV (against accelerators)

Peha-soft[®] syntex 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[®] syntex 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[®] syntex powder-free therefore is ensured if the product is used in line with the intended purpose.

2. Application / Indication

For examinations requiring high haptic sensation and excellent wearing comfort, especially suitable for persons disposed to allergy against latex proteins (allergy type I) or accelerators (allergy type IV).

3. Presentation (packaging)

non-sterile

• to be taken out of dispenser by piece

packaging material: latex-free

colour code of the packaging: yellow

transport carton dimension: 35.9 x 26.0 x 23.5 cm (L x W x H)
dispenser dimension: 22.0 x 12.5 x 6.8 cm (L x W x H)

size	reference number	dispenser	transport carton
XS (5.5 – 6.0)	942 164/1	100 pairs	10
S (6.5 – 7.0)	942 165/1	100 pairs	10
M (7.5 – 8.0)	942 166/1	100 pairs	10
L (8.5 – 9.0)	942 167/1	100 pairs	10
XL (9.5 – 10.0)	942 168/1	100 pairs	10



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4. Product Characteristics

material composition:

material: synthetic Polyvinyl chloride with softening agent and interior

polymer coating

• softening agents: Phthalate (Diisononylphthalate/DINP)

→ If required, HARTMANN certainly helps with further details.

product design:

colour: latex-colour

surface structure: smooth (non-textured)

grip strength: mediuminterior coating: polymer

• 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	75 ± 5	85 ± 5	95 ± 5	105 ± 5	115 ± 5

• film thickness (average values):

cuff	palm	finger tip
0.09 mm	0.11 mm	0.08 mm



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material characteristis:

tear strength/force at break:			
	norm requirement (EN 455-2)	average values for Peha-soft syntex powder-free, non-sterile	
Throughout shelf life and within 12 months of manufacture after challenge testing	≥ 3.6 N	3.8 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 from 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. <u>Labelling</u>

Lot-No. with 9-digit code: e.g. 8 XXX XX XX

year internal key

expiry date: e.g.: **2** 2011 06

year month

shelf life: 3 years



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7. Packaging

Peha-soft syntex powder-free gloves are available in dispenser boxes; dispenser boxes are packed in transport carton acc. DIN; sealed with adhesive tapes; packed on euro-pallets.

Date: 2013-12-12

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

i. A.

Eugen Grummann

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