

Peha-soft® syntex powder-free, latex-free (Stretch-Vinyl) non-sterile		Spec.-No.:	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: medium
- interior 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

		<h1>Technical Data Sheet</h1>
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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.



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