

Technical Data Sheet

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

	SpecNo.:	D 9.5031
Riterative W	Department:	CMO-DOE
\rightarrow	Date:	2013-07-17

1. General Product Description

- powder-free synthetic examination glove, for single use; non-sterile; made of synthetic vinyl; transparent
- medical product class I
- tear resistant and safe
- good 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[®] vinyl 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[®] vinyl 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[®] vinyl powder-free, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

For examinations in the medical field requiring good fit and touch sensitivity; especially suitable for persons disposed to allergy against latex proteins (allergy type I) or accelerators (allergy type IV).

3. Presentation (packaging)

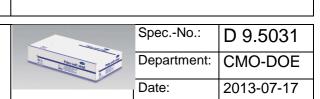
- non-sterile
- to be taken out of dispenser by piece
- packaging material: latex-free
- colour code of the packaging: violet
- transport carton dimension: Control digit /8
 - dispenser dimension: Control digit /4

Control digit /8 Control digit /4 $\begin{array}{l} 26.0 \text{ cm x } 23.5 \text{ cm x } 35.9 \text{ cm } (\text{L x W x H}) \\ 28.7 \text{ cm x } 25.0 \text{ cm x } 36.5 \text{ cm } (\text{L x W x H}) \\ 22.0 \text{ cm x } 12.5 \text{ cm x } 6.8 \text{ cm } (\text{L x W x H}) \\ 23.0 \text{ cm x } 13.4 \text{ cm x } 6.8 \text{ cm } (\text{L x W x H}) \end{array}$

size	reference number	dispenser	transport carton
XS (5.5 – 6.0)	942 169/8	100 pieces	10
S (6.5 – 7.0)	942 170/4 942 170/8	100 pieces	10
M (7.5 – 8.0)	942 171/4 942 171/8	100 pieces	10
L (8.5 – 9.0)	942 172/4 942 172/8	100 pieces	10
XL (9.5 – 10.0)	942 173/8	100 pieces	10

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4. **Product Characteristics**

material composition:

- material: Polyvinylchloride with softening agent and interior polymer coating
- softening agent: Phtalates (Diisononylphthalate/DINP)

 \rightarrow If required, HARTMANN certainly helps with further details.

product design:

- colour:
- surface structure:
- grip strength:
- smooth (non-sterile) medium

transparent

- interior coating: form:
- polymer to be worn left or right
- cuff: beaded
- overall length and overall width (according to EN 455-2):

size	XS	S	М	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 ± 0,03	0.011 mm ± 0,03	0.10 mm ± 0,03	

material characteristics:

tear strength/force at break:				
	norm requirement (EN 455-2)	average values for Peha-soft vinyl powder-free, non-sterile		
before ageing	≥ 3.6 N	3.7 N		
after ageing	≥ 3.6 N	3.6 N		

→ recent test results available on request



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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

 \rightarrow recent test results available on request

6. Labelling

Lot-No. with 9-digit code:	e.g.	8 year	XXX X interna	XX XX X Ikey
manufacturing date:	e. g.	쎄 year	2008 month	06
expiry date:	e.g.:	X	2011 year	06 month
shelf life:	3 years	S		



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7. Packaging

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

Date: 2013-07-17

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

i. A.

human

Eugen Grummann