



Technical Data Sheet

Peha-soft nitrile white,
powderfree, latexfree (nitrile), unsterile

Spec.-No.:	D 8.0007
Department:	CMO-DOE
Date:	2015-06-29

1. General Product Description

- powder-free examination and personal protection glove, for single use; non-sterile; made of synthetic nitrile; white; latex-free
- medical product class I
- personal protection equipment (PPE) category III
- textured fingers for excellent touch sensitivity and grip
- highly elastic and tear resistant
- excellent fit and comfort
- free of allergy risk against latex proteins (allergy type I)
- to be worn left and right
- approved for food contact

Peha-soft® nitrile white carries the CE mark according to EU directive 93/42/EEC for medical devices and the CE mark according to EU directive 89/686/EEC for Personal Protection Equipment. The product is classified as a class I medical device and category III personal protection equipment. A conformity assessment has been performed for Peha-soft® nitrile white, powder-free and it has been shown to be in compliance with all applicable requirements of the above mentioned directives. The safe use and effectiveness of Peha-soft® nitrile white, 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 excellent wearing comfort and high sensitivity is requested; particularly for users and patients with allergy against latex proteins (allergy type I). Additionally qualified as personal protection equipment and therefore applicable for cleaning and disinfection with chemicals and disinfections. Further suitable for usage in kitchens as qualified for food contact.

3. Presentation (packaging)

- non-sterile
- to be taken out of dispenser by piece
- packaging material: latex-free
- colour code of the packaging: pink

- transport carton dimension for P100: 29,6 cm x 22,9 cm x 23,0 cm (L x B x H)
- dispenser dimension for P100: 22,0 cm x 11,0 cm x 5,6 cm (L x B x H)
- transport carton dimension for P200: 35,0 cm x 25,5 cm x 25,0 cm (L x B x H)
- dispenser dimension for P200: 24,0 cm x 12,5 cm x 6,8 cm (L x B x H)



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size	reference number	dispenser	transport carton
XS (5 – 6)	942 205/2	200 gloves	10
S (6 – 7)	942 206/2	200 gloves	10
M (7 – 8)	942 207/2	200 gloves	10
L (8 – 9)	942 208/2	200 gloves	10
XL (9 – 10)	942 209/2	180 gloves	10
S (6 – 7)	942 216/2	100 gloves	10
M (7 – 8)	942 217/2	100 gloves	10
L (8 – 9)	942 218/2	100 gloves	10

4. Product Characteristics

material composition:

- material: synthetic nitrile rubber with polymer coating
- accelerators: type of carbamates
free of thiurames and mercaptobenzothiazoles (MBT)
- antioxidants: phenolic antioxidants

→ If required, HARTMANN certainly helps with further details.

product design:

- colour: white
- surface structure: textured fingers
- grip strength: medium
- interior coating: chlorinated
- exterior 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	≤ 80	86 ± 5	98 ± 5	107 ± 5	115 ± 5



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- film thickness (average values):

testing method	cuff	palm	finger tip
Single film thickness	0.05 mm	0.07 mm	0.09 mm

material :characteristics:

tear strength / force at break		
	Norm requirement (EN 455-2)	average values for Peha-soft nitrile white
Throughout shelf life and within 12 months of manufacture after challenge testing	≥ 6 N	≥ 6 N

→ recent test results available on request

5. Product Requirements

The gloves comply with the essential requirements of

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

The gloves comply with the essential requirements of protective gloves against chemicals and micro-organisms.

EN 374-1	Terminology and performance requirements
EN 374-2	Determination of resistance to penetration
EN 374-3	Determination of resistance to permeation by chemicals
EN 420	Requirements and test methods of protective gloves
EN 388	Marking and levels of performance of protective gloves

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6. Labelling

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

expiry date: e.g.:  2014 06
year month

shelf life: 3 years

7. Packaging

Peha-soft® nitrile white gloves are available in dispenser boxes; dispenser boxes are packaged in transport cartons acc. DIN; sealed with adhesive tapes; packaged on euro-pallets.

Date: 2015-06-29

PAUL HARTMANN AG
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CMO-Development Packaging Medical Supply (CMO-DPM)

i. A.



Dr. Siegfried Kumpf