



# Technical Data Sheet

**Peha-soft nitrile fino**  
**Powder-free, latex-free (nitrile)**  
**non sterile**



Spec.-No.:	D 8.0005
Department:	CMO-DOE
Date:	2015-06-29

## 1. General Product Description

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

Peha-soft® nitrile fino 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.

Furthermore, Peha-soft® nitrile fino powder-free carries the CE mark according to EU directive 89/686/EEC for Personal Protective Equipment. The product is classified as personal protective equipment category III.

A conformity assessment has been performed for Peha-soft® nitrile fino, 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 fino, 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 protective equipment and therefore applicable for cleaning and disinfection with chemicals and disinfectants. 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: purple
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- transport carton dimension: 35.0 cm x 25.5 cm x 25.0 cm (L x W x H)
  - dispenser dimension: 24.0 cm x 12.5 cm x 6.8 cm (L x W x H)



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size	reference number.	dispenser	transport carton
XS (5 – 6)	942 195/4	150 pieces	10
S (6 – 7)	942 196/4	150 pieces	10
M (7 – 8)	942 197/4	150 pieces	10
L (8 – 9)	942 198/4	150 pieces	10
XL (9 – 10)	942 199/4	150 pieces	10

#### 4. Product Characteristics

##### material composition:

- material: synthetic nitrile rubber
- accelerators: type of carbamates  
free of thiurames and mercaptobenzothiazole (MBT)
- antioxidants: phenolic antioxidants

→ If required, HARTMANN certainly helps with further details.

##### product design:

- colour: purple
- 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 ± 5	85 ± 5	95 ± 5	106 ± 5	115 ± 5

- film thickness (average values in mm):

Testing method	cuff	palm	finger tip
Single film thickness	0.05 mm	0.07 mm	0.11 mm



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material: characteristics:

tear strength / force at break		
	norm requirement (EN 455-2)	average values for Peha-soft nitrile fino, powder-free, non-sterile
Throughout shelf life and within 12 months of manufacture after challenge testing	≥ 6.0 N	7.6 N

→ recent test results available on request

5. Product Requirements

Peha-soft® nitrile fino powder-free complies 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 essential requirements of protective gloves

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

→ recent test results available on request

6. Labelling

Lot-No. with 9-digit code:	e.g. 1 year	XXX XX XX X	internal key
expiry date:	e.g. ⌚	2014 06	year month
shelf life:	3 years		



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## 7. Packaging

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

Date: 2015-06-29

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i. A.

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