
		Technical Data Sheet		
Peha-soft® nitrile FINO			Spec.-No.:	D 8.0005
			Department:	CEO-DOE
			Date:	2019-07-03

1. General Product Description

- Powder-free examination and personal protective glove, for single use; non-sterile; made of synthetic nitrile; purple-coloured; latex-free
- medical device class I
- personal protective equipment (PPE) category III
- textured fingertips for good tactile sensitivity and optimized grip
- highly elastic and tear resistant
- optimal fit and high comfort
- free of allergy risk against latex proteins (allergy type I)
- ambidextrous
- approved for food contact

Peha-soft® nitrile FINO is classified as a class I medical device and as category III personal protective equipment. A conformity assessment has been performed for Peha-soft® nitrile FINO and it has been shown to be in compliance with all requirements of the applicable directives and regulations of the European Union.

The safe use and effectiveness of Peha-soft® nitrile FINO is therefore ensured, if the products are used in line with the intended purpose.

2. Application / Indication

Examination gloves are single-use medical devices for prevention of infections, germ transmission and cross contamination during medicinal procedures/interventions. Used by healthcare professionals and lay users, in professional healthcare situations and in home environment.

Additional intended use as personal protective equipment. Protective gloves against dangerous chemicals and micro-organisms. Also suitable for food contact.

3. Presentation (packaging)


- non-sterile
- colour code of the packaging: purple

Peha-soft® nitrile FINO for P150:

- transport carton dimension: 35,0 cm x 25,5 cm x 25,0 cm (L x B x H)
- dispenser dimension: 24,0 cm x 12,5 cm x 6,8 cm (L x B x H)

Peha-soft® nitrile FINO for P10:

- transport carton dimension: 36,9 cm x 21,5 cm x 12,9 cm (L x B x H)
- dispenser dimension: 8,9 cm x 4,0 cm x 10,6 cm (L x B x H)

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size	reference number.	dispenser	transport carton
XS (5 – 6)	942 195/5	150 pieces	10
S (6 – 7)	942 196/5	150 pieces	10
M (7 – 8)	942 197/5	150 pieces	10
L (8 – 9)	942 198/5	150 pieces	10
XL (9 – 10)	942 199/5	150 pieces	10
S (6 – 7)	942 220/2	10 pieces	20
M (7 – 8)	942 221/2	10 pieces	20
L (8 – 9)	942 222/2	10 pieces	20

4. Product Characteristics

material composition:

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

→ If required, HARTMANN certainly helps with further details.

product design:

- colour: purple
- surface structure: textured fingers
- interior coating: chlorinated
- form: ambidextrous
- 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

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- film thickness (average values in mm):

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

material characteristics:

tear strength / force at break		
	standard requirement (EN 455-2)	average values for Peha-soft® nitrile FINO
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 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
EN 420:	Protective gloves- General requirements and test methods
EN ISO 374-1:	Terminology and performance requirements for chemical risks
EN 374-2:	Determination of material resistance to penetration
EN 16523-1:	Determination of material resistance to permeation by chemicals
EN 374-4:	Determination of material resistance to degradation by chemicals
EN ISO 374-5:	Terminology and performance requirements for micro-organisms risks
ASTM F1671 / ISO 16604:	Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System (viral penetration)
EN 421:	Protective gloves against ionizing radiation and radioactive contamination (radioactive contamination protection only)


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6. Labelling

Lot-No. with 9-digit code: e.g. **LOT** 8 XXX XX XX X
year internal key

manufacturing date: e. g.  2014 01
year month

expiry date: e.g.  2019 02
year month

shelf life: 3 years

7. Packaging

Peha-soft® nitrile FINO is available in dispenser boxes; dispenser boxes are packaged in transport cartons; sealed with adhesive tapes; packed in euro-pallets.

Date: 2019-07-03

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

i. A.



Patrick Lohrmann