

		Technical Data Sheet	
Peha-soft® nitrile STERILE		Spec.-No.:	D 8.0008
		Department:	CEO-DOE
		Date:	2019-07-03

1. General Product Description

- sterile powder-free examination and personal protective glove, for single use; made of synthetic nitrile rubber; blue-coloured; latex-free
- medical device class I sterile
- personal protective equipment (PPE) category III
- textured fingers 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
- packed in pairs in wrapping paper in peel pouches

Peha-soft® nitrile STERILE is classified as a class I sterile medical device and as category III personal protective equipment. A conformity assessment has been performed for Peha-soft® nitrile STERILE 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 of Peha-soft® nitrile STERILE is therefore ensured, if the product is used in line with the intended purpose.

2. Application / Indication

Sterile examination gloves are single-use medical devices for prevention of infections, germ transmission and cross contamination during medicinal procedures/interventions, which require sterile devices. 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.

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3. Presentation (packaging)

- sterile
- packed in pairs in wrapping paper and sealed in peel pouch
- colour code of the packaging: purple
- transport carton dimension: 27.8 cm x 24.2 cm x 34.3 cm (L x W x H)
- dispenser dimension: 23.6 cm x 13.5 cm x 16.5 cm (L x W x H)

size	reference number	dispenser	transport carton
S	942 211/3	50 pairs	4
M	942 212/3	50 pairs	4
L	942 213/3	50 pairs	4

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: blue
- surface structure: textured fingers
- interior coating: chlorinated
- form: ambidextrous
- cuff: beaded
- overall length and overall width (according to EN 455-2):

size	S	M	L
length: mm (min.)	240	240	240
width: mm	86 ± 5	98 ± 5	107 ± 5

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- film thickness (average values in mm):

Testing method	cuff	palm	finger tip
Single film thickness	0.07 mm	0.09 mm	0.12 mm

material characteristics:

tear strength / force at break		
	standard require- ment (EN 455-2)	average values for Peha-soft® nitrile STERILE
Throughout shelf life and within 12 months of manufacture after challenge testing	≥ 6 N	9 N

→ recent test results available on request

5. Product Requirements

The gloves comply with the requirements of following standards:

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)

→ recent test results available on request

