		Technical Data Sheet	
Peha-soft® nitrile GUARD		Spec.-No.:	D 8.0006
		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 rubber; blue-coloured; latex-free
- medical device class I
- personal protective equipment (PPE) Category III
- textured fingers for good tactile sensitivity and optimized grip
- long cuffs
- 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 GUARD 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 GUARD 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 GUARD is therefore ensured, if the product is 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: aqua blue
- transport carton dimension: 35.8 cm x 23.3 cm x 27.2 cm (L x W x H)
- dispenser dimension: 26.0 cm x 11.0 cm x 6.8 cm (L x W x H)

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size	reference number	dispenser	tansport carton
XS (5 - 6)	942 200/2	100 pieces	10
S (6 - 7)	942 201/2	100 pieces	10
M (7 - 8)	942 202/2	100 pieces	10
L (8 - 9)	942 203/2	100 pieces	10
XL (9 - 10)	942 204/2	100 pieces	10

#### 4. Product Characteristics

##### material composition:

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

→ If required, HARTMANN certainly helps with further details.

##### product design:

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

size	XS	S	M	L	XL
length: mm	290	290	290	290	290
width: mm	76 ± 4	86 ± 4	98 ± 4	107 ± 4	115 ± 4

- film thickness (average values in mm):

Testing method	cuff	palm	fingertip
Single film thickness	0.08 mm	0.10 mm	0.14 mm

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#### material characteristics:

tear strength / force at break		
	standard requirement (EN 455-2)	average values for Peha-soft® nitrile GUARD
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

Peha-soft® nitrile GUARD comply with the essential requirements of the 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

## 6. Labelling

Lot-No. with 9-digit code:	e.g.		8	XXX XX XX X
			year	internal key
manufacturing date:	e. g.		2014	01
			year	month
expiry date:	e.g.		2019	02
			year	month

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shelf life: 3 years

#### 7. Packaging

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

Date: 2019-07-03

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i. A.



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