HARTMANN		Technical Data Sheet

Peha-micron® LATEX		Spec.-No.:	D 6.5581
		Department:	CEO-DOE
		Date:	2019-05-01

1. General Product Description

- powderfree surgical gloves, for single use; sterile; made of thin and soft natural rubber latex; with polymer coating
- medical device class IIa
- personal protective equipment category III
- thin for good tactile sensitivity
- translucent brown coloured, avoids light reflection
- good tactile sensitivity, optimised grip, micro rough surface; highly elastic and tear resistant; anatomic shape

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

2. Application / Indication

In general, surgical gloves are single-use products for usage in all kinds of surgical procedures.

Surgical gloves are single-use sterile surgical gloves for short-term prevention of infections, germ transmission, and cross contamination during medicinal procedures/interventions in clinical and home
environment. Surgical gloves can be applied (optional) in combination with a second pair of operation gloves as an underglove.

Additional intended use as personal protective equipment. Protective gloves provide limited protection against hazardous substances.

3. Presentations (packaging)

- sterile
- with turned up cuff
- packed in pairs in inner wrapping paper and sealed in easy to open peel pouch
- colour code of the packaging: brown

- transport carton dimension: 52.7 cm x 25.7cm x 23.3cm (L x W x H)
- dispenser dimension: 25.0 cm x 12.9 cm x 22.5 cm (L x W x H)

size	reference number	dispenser	transport carton
5.5	942 570/4	50 pairs	4

6.0	942 571/4	50 pairs	4
6.5	942 572/4	50 pairs	4
7.0	942 573/4	50 pairs	4
7.5	942 574/4	50 pairs	4
8.0	942 575/4	50 pairs	4
8.5	942 576/4	50 pairs	4
9.0	942 577/4	50 pairs	4

4. Product Characteristics

material composition:

- material: modified natural rubber (produced from natural latex) with interior polymer coating
- accelerators: type of carbamates
  free of thiurames und mercaptobenzothiazoles
- antioxidants: phenolic derivative
- water-soluble proteins:

  recent test results available on request

EN 455 requirement	average values
< 50 µg/g	Modified Lowry < 30 µg/g HPLC Method < 30 µg/g

→ If required, HARTMANN certainly helps with further details.

product design:

- colour: brown
- surface structure: micro rough
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- interior coating: polymer
- form: full anatomic
- cuff: beaded

- overall length and overall width (according to EN 455-2):

size	**5.5**	**6.0**	**6.5**	**7.0**	**7.5**	**8.0**	**8.5**	**9.0**
length: mm (min.)	290	290	290	290	290	290	290	290
width: mm	68 - 76	72 – 82	78 – 88	84 – 94	90 – 100	96 – 108	102 - 114	108 - 120

- film thickness (average values):

	cuff	palm	finger tip
Single wall thickness	0.16 mm	0.17 mm	0.18 mm
Double wall thickness	0.32 mm	0.34 mm	0.36 mm

material characteristics:

tear strength/force at break:		
	standard requirement (EN 455-2)	average values for Peha®-micron LATEX
Throughout shelf life and within 12 months of manufacture after challenge testing	≥ 9 N	14 N

→ recent test results available on request

5. Product Quality

The gloves comply with the essential requirements as medical devices and the standards:

EN 455-1:	Requirements and testing for freedom of holes (AQL ≤ 1.5) The HARTMANN minimum request is AQL ≤ 0.65
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.	LOT	8 year	XXX XX XX X internal key
manufacturing date:	e. g.		2014 year	01 month
expiry date:	e.g.		2019 year	02 month
shelf life:	5 years			

7. Packaging

Peha-micron® LATEX gloves are sealed in pairs and available in dispenser boxes; 4 dispenser boxes are packaged in one transport carton; sealed with adhesive tapes; packed on euro-pallets.

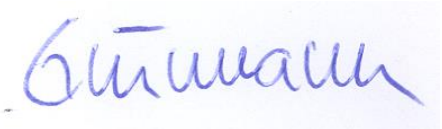
8. Sterilisation

Gamma-sterilisation according to DIN EN ISO 11137 and EN 552; min. 25 kGy

Date: 2019-05-01

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

i. A.



Eugen Grummann