

		<h1>Technical Data Sheet</h1>
---	--	-------------------------------

<h2>Peha-basic® LATEX</h2>		Spec.-No.:	D 6.5586
		Department:	COE-DOE
		Date:	2019-05-01

1. General Product Description

- powderfree surgical gloves, for single use; made of thin and soft natural rubber latex
- medical product class IIa
- personal protective equipment category III
- micro rough surface and good tactile sensitivity, highly elastic and tear resistant; full anatomic shape

Peha-basic® 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-basic® 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 of Peha-basic® 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. Presentation (packaging)

- sterile
- with turned up cuff
- packed in pairs in wrapping paper and sealed in easy to open peel pouch
- colour code of the packaging: red
- transport carton dimension: 52.7 cm x 25.7 cm x 23.3 cm (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	942 500/2	50 pairs	4
6.0	942 501/2	50 pairs	4

Peha-basic® LATEX		Spec.-No.:	D 6.5586
		Department:	COE-DOE
		Date:	2019-05-01

6.5	942 502/2	50 pairs	4
7.0	942 503/2	50 pairs	4
7.5	942 504/2	50 pairs	4
8.0	942 505/2	50 pairs	4
8.5	942 506/2	50 pairs	4
9.0	942 507/2	50 pairs	4

4. Product Characteristics

material composition:

- material: modified natural rubber (produced from natural latex)
- accelerators: type of carbamates
free of thiurames and 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: latex-white to yellow
- surface structure: micro rough
- interior coating: chlorination
- 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	72 ± 4	77 ± 5	83 ± 5	89 ± 5	95 ± 5	102 ± 6	108 ± 6	114 ± 6

- film thickness (average values):

	cuff	palm	finger tip
--	------	------	------------

		Technical Data Sheet
---	--	----------------------

Peha-basic® LATEX		Spec.-No.:	D 6.5586
		Department:	COE-DOE
		Date:	2019-05-01

Single wall thickness	0.16 mm	0.18 mm	0.20 mm
Double wall thickness	0.32 mm	0.36 mm	0.40 mm

material characteristics:

tear strength/force at break:		
	standard requirement (EN 455-2)	average values for Peha®-basic LATEX
Throughout shelf life and within 12 months of manufacture after challenge testing	≥ 9.0 N	15 N

→ recent test results available on request

5. Product Requirements


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 XXX XX XX X
year internal key

		Technical Data Sheet
---	--	----------------------

Peha-basic® LATEX		Spec.-No.:	D 6.5586
		Department:	COE-DOE
		Date:	2019-05-01

manufacturing date: e. g.  2014 01
year month

expiry date: e.g.  2019 02
year month

shelf life: 5 years

7. Packaging

Peha-basic® 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 556; min. 25 kGy.

Date: 2019-05-01

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

i. A.



Eugen Grumann