


Peha-shield® powderfree, latex sterile		Spec.-No.:	D 9.5231
		Department:	CMO-DOE
		Date:	2014-06-03

1. General Product Description

- powderfree surgical gloves, for single use, sterile, with a shielding effect against scattered X-rays
- made of thin natural rubber latex and lead-free metal oxide (Bismuth(III) oxide)
- very good touch sensitivity, highly elastic and tear resistant, no tiring of fingers due to full anatomic shape
- green coloured to avoid light reflection
- personal protective equipment (PPE) category III

Peha-shield® powderfree carries the CE mark according to EU directive 89/686/EEC for Personal Protective Equipment. The product is classified in category III. A conformity assessment has been performed for Peha-shield® powderfree and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of Peha-shield® powderfree, therefore, is ensured if the product is used in line with the intended purpose.


2. Application / Indication

For protection against scattered X-rays radiation produced by apparatus used during medical procedures, such as diagnostic cardiac catheterisation, angiography, surgery, orthopaedics, etc.

3. Presentation (packaging)

- sterile
- packed in pairs in inner wrapping paper and sealed in easy to open PE-peelpouch
- packaging materials: latex-free
- colour code of the packaging: aqua
- transport carton dimension: 29.7 cm x 16.1 cm x 23.2 cm (L x W x H)
- dispenser dimension: 29.0 cm x 16.0 cm 5.5 cm (L x W x H)

size	reference number	dispenser	transport carton
6.5	942 880/1	5 pairs	4
7.0	942 881/1	5 pairs	4
7.5	942 882/1	5 pairs	4
8.0	942 883/1	5 pairs	4
8.5	942 884/1	5 pairs	4
9.0	942 885/1	5 pairs	4

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4. Product Characteristics

material composition:

- material: modified natural rubber (produced from natural latex) with metal oxide filling with interior polymer coating
- attenuation reducer: Bismuth(III) oxide (no lead!)
- accelerators: type of Carbamates
free of Thiurames and Mercaptobenzothiazoles
- antioxidants: phenolic derivate
- water-soluble proteins: according to EN 455-3 < 50 µg/g
recent test results (Modified Lowry, HPLC-Method) on request

→ If required, HARTMANN certainly helps with further details.

product design:

- colour: greenish
- surface structure: textured
- grip level: medium
- interior coating: polymer
- form: full anatomic
- cuff: beaded

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

size	6.5	7.0	7.5	8.0	8.5	9.0
length: mm (min.)	265	270	270	270	280	280
width: mm	83 ± 4	89 ± 4	95 ± 5	102 ± 5	108 ± 5	114 ± 6

- film thickness (average values):

cuff	palm	finger tip
min. 0.30 mm	min. 0.28 mm	min. 0.30 mm

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material characteristics:


tear strength/force at break:		
	norm requirement (EN 455-2)	average values for Peha-shield powderfree, sterile
Throughout shelf life and tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0 N	19 N

→ recent test results, available on request

Radiation attenuation:

The listed values correspond to the nominal material thickness of 0.30 mm.
 Measurements in accordance with ICRP 60 and ICRU 51 (measured by the Landesamt für Arbeitsschutz (LfAS), Munich).

Parameter	Measured value	Test conditions	Remarks
Lead equivalence value according to DIN/IEC: [mm Pb]	0,045	80 kVp, 2.5 mm Al + 0.15 mm Cu, small field	Finger/hand (average), according to DIN 6845/IEC 61331-1
Attenuation of skin dose H'(0,07), scattered radiation	60 kV 58 % 80 kV 48 % 100 kV 39 %	60/80/100 kV, 2.5 mm Al scattered beam from water phantom according to DIN 6815 Field size 25x25cm Indicator: H'0,07 according to ICRU	Finger Measured 5cm sideways of the
Attenuation of skin dose H'(0,07), primary radiation beam	60 kV 46 % 80 kV 37 % 100 kV 30 %	60/80/100 kV, Water phantom according to DIN, Indicator: H'0,07	

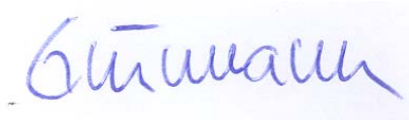
		<h1>Technical Data Sheet</h1>
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