


Foliodress® caps comfort Universal		Spec.-No.:	D 9.5102a
		Department:	SM-PDO
		Date:	2012-10-23

1. General Product Description

Foliodress® caps comfort Universal nursery cap made of breathable and skin-friendly polypropylene nonwoven fabric in beret-form with latex-free elastic-band.

Foliodress® caps comfort Universal carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class I medical device.

A conformity assessment has been performed for Foliodress® caps comfort Universal and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use and effectiveness of Foliodress® caps comfort Universal, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Especially light cap for single use in the operating theatre; suitable for head covering of patients.

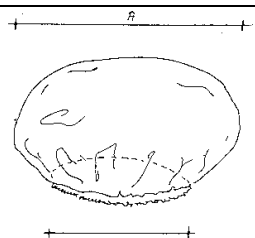
3. Presentations

Article No	992 466	white	100 pieces / folding box
	992 465	green	100 pieces / folding box

4. Product Characteristics

Material:	14gsm 100% Polypropylene spunbond
Elastic threads:	Free of natural rubber latex
Tensile strength: - length	appr. 21 N/50 mm

5. Product Requirements

Universal			
In beret-form with latex-free elastic-band.			
	Diameter:	A	520 ± 10 mm
	Elastic band:	B	185 ± 13 mm

		Technical Data Sheet
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6. Labelling

Lot-No. with 9-digit code:

e.g.:

LOT	8	013	XXXXX
	year	production order	for internal purposes only

Expiry date:

e.g.: ⌚ 2013 12
 year month

Shelf life: 5 years

7. Packaging

In dispenser boxes; packed into transport carton; transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

Date: 2010-10-23

PAUL HARTMANN AG
- SM-PDO Solution Management
- Product Development OR-Management

i. A.



Dr. Silke Wolfrum