

Foliodress® Patient Kit Plus - Patient clothing kit (including underpants)

Spec.-No.: D 1.0411a

Department: CMO-DOE

Date: 2014-04-28

1. General Product Description

Single use patient clothing kit consisting of:

- Nonwoven shirt for single use. Short sleeves and rounded neck, open down the back over the total length. Fastening belts at neck and waist.

Colour: navy blue.

- Nonwoven round cap for single use, with elastic edges. Permeable to air.

Colour: light blue.

- Nonwoven overshoes for single use, with elastic hem inside at the ankle and rounded edges.

Colour: white.

- Nonwoven underpants for single use with elastics at the waist and thighs.

Colour: navy blue.

Medinette® B cap comfort 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 Medinette® B cap comfort and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Medinette® B cap comfort, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Clothing for a patient, who has to undergo an operation or an examination.

3. Presentations

Article No.	992 603	Foliodress® Patient-Kit Plus	packed in PE bag, 1 kit per bag, 50 bags per carton
		dimension of carton	500x300x360 mm

4. Product Characteristics

Material: Nonwoven: 100% polypropylene (patient shirt: about 38 g/m²; cap: about 12 g/m²; overshoes: about 35 g/m²; underpants: about 38 g/m²).
Latex-free elastics.

Elastic band: Made of synthetic rubber, latex-free

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5. Product Requirements

- Patient shirt:
Height: about 110 cm
Circumference: about 140 cm

- Cap (see illustration):
A: about 30 cm
B: about 12 cm

- Overshoes:
Opening ankle: about 13 cm
Total length: about 38 cm
Maximum height: about 18 cm

- Underpants (see illustration):
C: about 24 cm (stretchable width), about 54 cm (stretched width)
D: about 33 cm
E: about 12 cm

Latex-free.
Colophonium-free.



6. Labelling

Lot-No. with 15-digit code:

e.g.:	06	001	XXXX	21	01	14
	year	serial number	for internal purposes only	day of production	month of production	year of production

7. Packaging

1 kit in PE-bag; 50 PE-bags are packed into transport carton; transport carton acc. European directive 94/62, sealed with adhesive tapes, packed onto euro pallet.

Date: 28.04.2014

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PAUL HARTMANN AG
- CMO-DOE
- Development Operating Theatre Management

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A handwritten signature in black ink, appearing to read "S. Wolfrum".

Dr. Silke Wolfrum