

Foliodress® Clean Air Suits



Spec.-No.: D 1.0407

Department: SM-PDO

Date: 2011-05-13

1. General Product Description

Foliodress® Clean Air Suits are made of water repellent, breathable nonwoven fabric with resistance to penetration by fluids and bacteria. The material is low-linting and abrasion-resistant. The pants have comfortable flowing ties within a guide at the waist. The short-sleeve tunic has a V-neck and two practical pockets.

Foliodress® Clean Air Suits carry 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® Clean Air Suits 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® Clean Air Suits, therefore, is ensured if the product is used in line with the intended purpose.

Foliodress® Clean Air Suits correspond to the requirements of the European Standard EN 13795 (1-3).

2. Application / Indication

As disposable operating theatre clothing.

3. Presentations

Sizes: S, M, L, XL, XXL

Colour: green / blue / pink

4. Product formation Foliodress® Clean Air Suits

Material:

- nonwoven PP-Nonwoven (SMMS), 45 g/m²
- sewing thread: 100 % Polyester or Nylon

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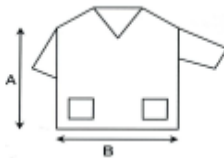


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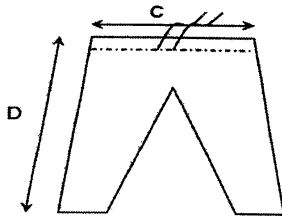
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5. Product Dimensions tunic (cm)



Size	S	M	L	XL	XXL
A	72	75	77	79	80
B	52	57	60	63	72

6. Product Dimensions pants (cm)



Size	S	M	L	XL	XXL
C	51	56	58	60	67
D	104	106	108	110	116

7. Product Requirements (typical readings)

Property	Test method	Unit	Requirements of EN 13795-3	Test results
Resistance to microbial penetration – Dry	EN ISO 22612	log ₁₀ (CFU)	≤ 2	< 1,0
Cleanliness - Microbial	EN 1174-2	log ₁₀ (CFU/dm ²)	≤ 2	< 2
Cleanliness – Particulate matter	ISO 9073-10	log ₁₀ (IPM)	≤ 3,5	< 2,0
Linting	ISO 9073-10	log ₁₀	≤ 4,0	< 2,5
Bursting strength - Dry	EN 13938-1	kPa	≥ 40	> 100
Tensile strength - Dry	EN 29073-3	N	≥ 20	> 30

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8. Labelling

Lot-No. with 13-digit code:

e.g.:

11	001	XXXX	21	01
year	serial number	for internal pur- poses only	day of production	month of production

9. Packaging

1 Suit is packed in a film bag, 50 bags per carton.

Transport carton according DIN, sealed with adhesive tapes, packed onto europallet.

Date: 2011-05-13

PAUL HARTMANN AG
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- Product Development OR-Management

i. A.



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