

Foliodress S – protective gown

Spec.-No.: D 9.5114c

Department: SM-PDO

Date: 2011-03-23

1. General Product Description

Foliodress S is a disposable protective gown, made of a blue nonwoven, with an open back, ties to adjust the neck and a belt tie at the waist. Elastic cuffs, overlock seams, crossed back.

Foliodress S carries the CE mark according to EU directive 93/42/EEC for medical devices. The product in non-sterile version is classified as a class I medical device, in sterile version as class I*.

A conformity assessment has been performed for Foliodress S 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 S, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

For single use of visitors and nursing staff; for the protection of patients.

3. Presentations

Foliodress S – protective gown, - unsterile: 10 gowns / PE-bag, 5 PE-bags / carton
- sterile: 1 gown / blister, 24 gowns / PE-bag,
2 PE-bags / carton

size: standard size
colour: blue

4. Product Characteristics

Material composition:

Nonwoven: 100 % polypropylene, 28 gsm

Elastic band: Synthetic rubber, free of natural rubber latex

Sewing threads: 100 % PES

Foliodress S contains no natural rubber latex and is colophony free.

Foliodress S – protective gown

Spec.-No.: D 9.5114c

Department: SM-PDO

Date: 2011-03-23

5. Product Requirements

Length: appr. 112 cm

Width: appr. 132 cm

Length of belt tie: appr. 200 cm

6. Labelling

Lot-No. with 9-digit code:
e.g.:

1	013	XXXXX
year	number of production order	for internal purposes only

7. Packaging

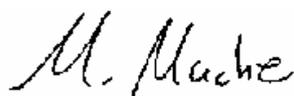
Unsterile protective gown: 10 Foliodress protective gowns in a sealed PE-bag;
5 bags per transport carton acc. DIN, sealed with adhesive tapes,
packed onto europallet.

Sterile protective gown: 1 Foliodress protective gowns in blister packaging,
24 gowns in a PE-bag, 2 PE-bags per transport carton acc. DIN,
sealed with adhesive tapes, packed onto europallet.

Date: 2011-03-23

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

i. A.



Marion Muche