

## Foliodress S protective gowns, impervious

Spec.-No.: D 9.5114d

Department: SM-PDO

Date: 2011-03-23

### 1. General Product Description

Foliodress S is a disposable protective gown, made of a white, impervious-laminate, 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 nursing staff, for the protection of patients during personal hygiene (Bathing, etc.)

### 3. Presentations

Foliodress S – protective gown, fluidproof,	- unsterile:	10 gowns / PE-bag, 5 PE-bags / carton
	- sterile:	1 gown / blister, 22 gowns / PE-bag, 2 PE-bags / carton

size:	standard size
color:	white

### 4. Product Characteristics

Material composition:

Nonwoven: PP – PE Laminate, 42 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 gowns,  
impervious**

Spec.-No.: D 9.5114d

Department: SM-PDO

Date: 2011-03-23

**5. Product Requirements****- Dimensions**

Length: appr. 122 cm

Width: appr. 137 cm

Length of belt tie: appr. 200 cm

**- Material properties:**

Resistance against Liquid penetration: (cm hydrohead) &gt; 100

Tensile strength: md (N/50 mm) > 39  
cd (N/50 mm) > 50**6. Labelling**

Lot-No. with 9-digit code:

e.g.:

1  
year013  
number of production  
orderXXXXX  
for internal purposes only

## Foliodress S protective gowns, impervious

Spec.-No.: D 9.5114d

Department: SM-PDO

Date: 2011-03-23

### 7. Packaging

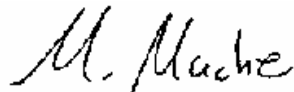
Unsterile protective gown: 10 protective gowns in a sealed PE-bag;  
5 bags per transport carton acc. DIN, sealed with adhesive tapes,  
packed onto europallet.

Sterile protective gown: 1 Foliodress protective gowns in blister packaging,  
22 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.

A handwritten signature in black ink, appearing to read "M. Muche".

Marion Muche