

## Foliodress<sup>®</sup> warming collar, unsterile



Spec.-No.: D\_65543-04  
Department: COM-DOE  
Date: 2018-11-23

### 1. General Product Description

Single use warming collar for usage in the operating theatre and other departments of healthcare facilities (e. g. hospitals, ambulant care centers highly intensive care units).

The products are delivered non-sterile, folded and 50 warming collars are packed into a Polyethylene (PE) bag together with a paper inlay and delivered in 6 bags per transport carton.



The warming collar is a fabric of rectangle shape with neck-wide cuff in the middle delivered in one size. It is offered in royal blue only.

The Foliodress warming collars are single-use scrub suit clothing made from spunbond-meltblown-spunbond (SMS) Polypropylen (PP) non-woven as main garment material.

Classification for non-sterile medical devices class I, acc. Directive 93/42/EEC.

### 2. Application / Indication / Contraindication

Foliodress warming collar is a single-use scrub suit for short-term use by health professionals in clinical environment (operating theatre and other departments of healthcare facilities, e.g., hospitals, ambulant care centers and highly intensive care units) to prevent infections and cross contaminations on humans.

Intended users are health care professionals such as OR surgeons, OR nurses, OR anesthetist, and guided OR visitors.

Non-sterile Foliodress warming collars are not intended to be worn in sterile operating area, (where sterile clothing shall be applied) – without coverage by a sterile surgical gown.

Foliodress warming collars are not intended for sterilization.

Foliodress Foliodress warming collars are single use products only and shall not be reused and/or shall be changed and disposed after contamination or damaging.

## Foliodress® warming collar, unsterile



Spec.-No.: D\_65543-04  
 Department: COM-DOE  
 Date: 2018-11-23

### 3. Product variants

Foliodress® warming collar					
Code	Colour	Size	Pieces /PE bag	PE bags /Carton	Total amounts /Carton
992 850/2	Royal blue	One size	50	6	300

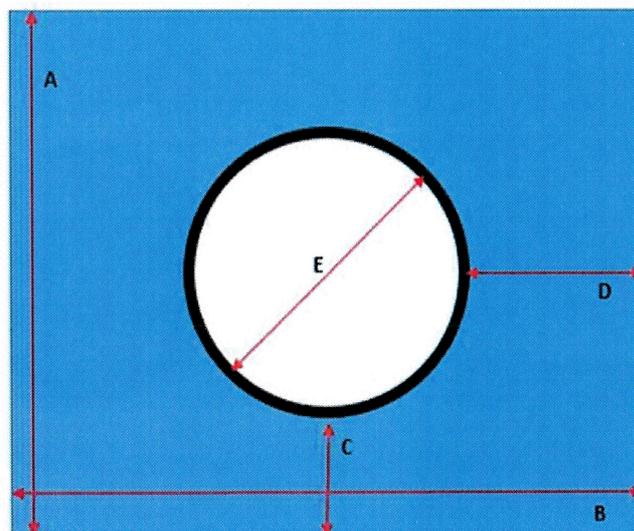


### 4. Product Characteristics

#### 4.1. Composition

Foliodress® warming collar contains no natural rubber latex and is colophony free.	
Nonwoven	Polypropylene-Nonwoven, 44 gsm, antistatic, water-absorbing
Sewing thread	Polyester
Body	Polypropylene (SMS non-woven)
Cuffs	Polyester

#### 4.2 Product dimensions Foliodress® warming collar [cm]



## Foliodress® warming collar, unsterile



Spec.-No.: D\_65543-04  
 Department: COM-DOE  
 Date: 2018-11-23

	Description	One size
A	Width of the collar body	45
B	Length of the collar body	55
C	Distance of the cuff to the long side of the collar body	14
D	Distance of the cuff to the short side of the collar body	19
E	Cuff diameter	17
F	Cuff length	5.5

### 5. Product Performance

The main garment material of Foliodress warming collar was tested according to following material performance requirements to prove material quality.

Property	Test method	Unit	Requirements <sup>a</sup>	Test results Blue collar
Resistance to microbial penetration – Dry	EN ISO 22612	CFU	≤ 300 <sup>b</sup>	127
Cleanliness – Microbial	EN ISO 11737-1	CFU/100 cm <sup>2</sup>	≤ 100 <sup>c</sup>	32
Cleanliness – Particulate matter	EN ISO 9073-10	IPM	≤ 3.5	1.8
Linting	EN ISO 9073-10	log <sub>10</sub> (lint count)	≤ 4.0	1.8
Bursting Strength – Dry	EN ISO 13938-1	kPa	≥ 40	134
Tensile strength – Dry	EN 29073-3	N	MD > 70 CD > 30	MD: 92.3 CD: 44.1

<sup>a</sup> Performance requirement of the main garment SMS material

<sup>b</sup> Test conditions: load concentration 10<sup>8</sup> CFU/g Talcum and vibration duration of 30 min.

<sup>c</sup> Total bioburden count of the whole garment

### 6. Labelling

Lot-No. with 9-digit code:  
 e.g.: 802302005

8	023	02	00	5
[8=2018]	[000-999]	[01-99]		
last digit of the current year	serial production order	supplier number	trading goods	control digit*

\* Variabel; based on leading digits

Expiry date:

e.g.: ⌚ 2018 – 12  
 year – month

Shelf life: 3 years

## Foliodress® warming collar, unsterile



Spec.-No.: D\_65543-04

Department: COM-DOE

Date: 2018-11-23

### 7. Packaging

Warming collars are packed in PE bags (50 pieces) and 6 bags are placed in one carton.

### 8. Storage conditions

Products shall be stored dry and protected from sunlight.



Date: 2018-11-23

PAUL HARTMANN AG  
COM-Development OTM & Exam. Gloves (COM-DOE)

i. A.

A handwritten signature in blue ink, appearing to read "K. Friedemann".

Dr. Kathrin Friedemann