HARTMANN		Technical Data Sheet

Foliodress® Protect, sterile		Spec.-No.:	D 6.0005
		Department:	CMO.DOE
		Date:	2015-01-09

1. General Product Description

Foliodress® Protect is a surgical gown made of fluid-repellent non-woven fabric with a microfibre middle layer; with high resistance to penetration by fluids and bacteria; low-linting and abrasion-resistant; with long and knitted elastic cuffs and secure Combitape to adjust the neck of the gown; different versions adapted to the needs depending on the duration of the procedure or the quantity of fluid.

Foliodress® Protect 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 Foliodress® Protect 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® Protect, therefore, is ensured if the product is used in line with the intended purpose.

Foliodress® Protect is made from materials which correspond to the requirements of the European Standard EN 13795:2011. Foliodress® Protect Standard is classified as standard – performance gown. A differentiation of critical and less critical areas is not implemented, the complete gown underlies the requirements for critical areas. Foliodress® Protect reinforced is classified as high- performance gown. For this gown sleeves and front are defined as critical areas, whereas the rest of the gown is less critical.

2. Application / Indication

For single use in surgical procedures only; exactly adapted to the different demands depending on the type of surgery, the quantity of fluid and the duration of the procedure:
- Foliodress Protect standard for protection during surgeries of short duration involving small quantities of fluids
- Foliodress Protect reinforced for protection during long surgeries involving moderate or large quantities of fluid

3. Product Characteristics

Composition:	
- nonwoven:	PP-Non-woven (SMMMS), blue, 40g/m²
- cuffs:	100 % Polyester
- reinforcement material:	Non-woven / film-laminate (PP/PE) in front and sleeves as additional protection against liquid penetration, 38g/m²
-combitape	Tape with hooks and adhesive area of polypropylene, hot melt
Foliodress® Protect contains no natural rubber latex and is colophony free.	

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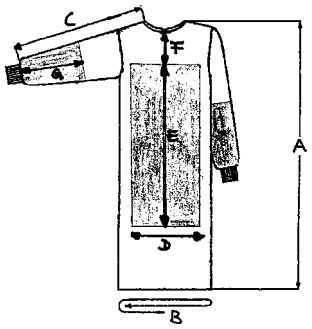
4. Product Requirements

4.1 Product dimensions Foliodress® Protect standard/reinforced



size:	A	B	C	D	E	F	G
M	115	150	69	40	80	10	32
L	125	157	80	50	90	10	40
XL	140	165	87	50	100	10	40
XXL	155	170	87	50	100	10	40

4.2 Product requirements (typical values): nonwoven (standard performance)

Property	Test method	Unit	Requirements of EN 13795 (critical areas)	Test results
Resistance to microbial penetration - Dry	EN ISO 22612	CFU	Not required	-
Resistance to microbial penetration - Wet	EN ISO 22610	I_B	≥ 2,8	2,8
Cleanliness - Microbial	EN ISO 11737-1	CFU/ 100cm²	≤ 300	Sterile!
Cleanliness – Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	1,9
Linting	EN ISO 9073-10	log_{10} (lint count)	≤ 4,0	outside: 2,3 inside: 2,0
Resistance to liquid pene-tration	EN 20811	cm H_2O	≥ 20	46,0
Bursting strength - Dry	EN ISO 13938-1	kPa	≥ 40	186,0
Bursting strength - Wet	EN ISO 13938-1	kPa	≥ 40	174,0
Tensile strength - Dry	EN 29073-3	N	≥ 20	cd: 48,2 md: 82,3
Tensile strength - Wet	EN 29073-3	N	≥ 20	cd: 48,1 md: 83,1

All data refer to sterile products!
Test results according to an external, independent and accredited test laboratory.
Test certificates available on request.

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4.3 Product requirements (typical values): reinforced area (front and sleeves, high performance)

Property	Test method	Unit	Requirements of EN 13795 (critical areas)	Test results
Resistance to microbial penetration - Dry	EN ISO 22612	CFU	not required	-
Resistance to microbial penetration - Wet	EN ISO 22610	I_B	6,0	6,0
Cleanliness - Microbial	EN ISO 11737-1	CFU/ 100cm²	≤ 300	Sterile!
Cleanliness – Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	1,7
Linting	EN ISO 9073-10	log_{10} (lint count)	≤ 4,0	outside: 1,9 inside: 1,9
Resistance to liquid pene-tration	EN 20811	cm H_2O	≥ 100	165,0
Bursting strength - Dry	EN ISO 13938-1	kPa	≥ 40	303,0
Bursting strength - Wet	EN ISO 13938-1	kPa	≥ 40	271,0
Tensile strength - Dry	EN 29073-3	N	≥ 20	md: 141,0 cd: 85,3
Tensile strength - Wet	EN 29073-3	N	≥ 20	md: 138,0 cd: 81,4

All data refer to sterile products!
Test results according to an external, independent and accredited test laboratory. Test certificates available on request, the shown values represent the average of all measurements.

5. Labelling

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

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

expiry date:
e.g.:

⌛ 2016 – 12
year – month

Shelf life:

The shelf life is 5 years.

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6. Packaging

Surgical gowns, with 2 towels and packed in CSR-wrap, individually sealed in sterile primary packaging; packed into polyethylene bags and transport carton; transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

Number of gowns / carton:

Size M : 36
Size L : 28
Size XL : 28
Size XXL : 28

7. Product codes

Product code	Product name	Size
992 144/6	Protect standard, C+T	M
992 145/6	Protect standard, C+T	L
992 146/6	Protect standard, C+T	XL
992 147/6	Protect standard, C+T	XXL
992 154/6	Protect reinforced, C+T	M
992 155/6	Protect reinforced, C+T	L
992 156/6	Protect reinforced, C+T	XL
992 157/6	Protect reinforced, C+T	XXL

Date: 2015-01-09

PAUL HARTMANN AG
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i. A.

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