



Foliodress® Comfort, sterile



Spec.-No.:	D 9.5111
Department:	CMO-DOE
Date:	2015-01-09

1. General Product Description

Foliodress® Comfort 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; with secure velcro fasteners (Foliodress® Comfort B) or Combitape (all other Foliodress® Comfort gowns) to adjust the neck of the gown; presentations well adapted to the needs depending on the duration of the procedure or the quantity of fluid.

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

Foliodress® Comfort OR-gowns correspond to the requirements of the European Standard EN 13795:2011. Foliodress® Comfort Basic and Perfect are classified as standard – performance gowns. A differentiation of critical and less critical areas is not implemented, the complete gown underlies the requirements for critical areas. Foliodress® Comfort Special and Comfort B 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; different packaging without inner crepe wrapping and towels are available for users preferring the “peel-and-go” version.

3. Presentations

Foliodress® Comfort basic: Sizes: L, XL	open-back gown closed by ties at the back
Foliodress® Comfort perfect: Sizes: M, L, XL, XXL	extra-wide overlapping at the back
Foliodress® Comfort special: Sizes: L, XL, XXL	extra-wide overlapping at the back, with reinforcement in the chest and sleeve area
Foliodress® Comfort B: Sizes: L, XL	extra-wide overlapping at the back, with reinforcement in the chest and sleeve area
Colour:	aqua



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4. Product Characteristics:

Composition:	
Foliodress® Comfort contains no natural rubber latex and is colophony free.	
- Nonwoven:	PP-Nonwoven (SMMMS), alcohol repellent and anti-static alcohol repellency (WSP 80.8 (2005)) > Level 8
- Cuffs:	100 % Polyester
- Sewing thread:	100 % Polyester
- Combitape (<u>not</u> Foliodress® Comfort B):	Tape with hooks and adhesive area of polypropylene, hot melt
- Hooks (<u>only</u> Foliodress® Comfort B):	Polyamide-woven
- Velour (<u>only</u> Foliodress® Comfort B):	Polyamide-warp knitted
- Additional protection against liquid penetration:	The front of Foliodress® Comfort special is reinforced with a breathable 2-layer laminate ("AirActiv-reinforcement") alcohol repellency at reinforced front area (WSP 80.8 (2005)) > Level 9, while the sleeves are made of a special, breathable 3-layer laminate alcohol repellency at reinforced sleeve area(WSP 80.8 (2005)) > Level 9

5. Product requirements

5.1 Product dimensions Foliodress® Comfort basic [cm]

	Size	B	C	D
	L	156	123	79
	XL	156	149	85



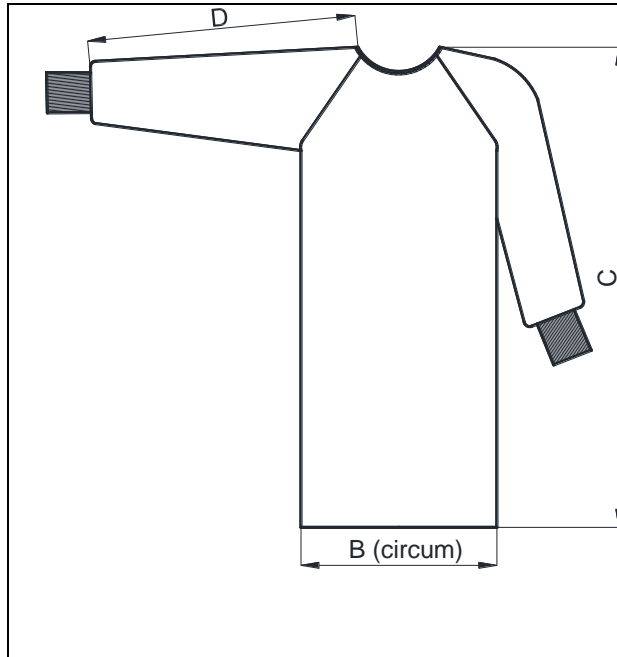
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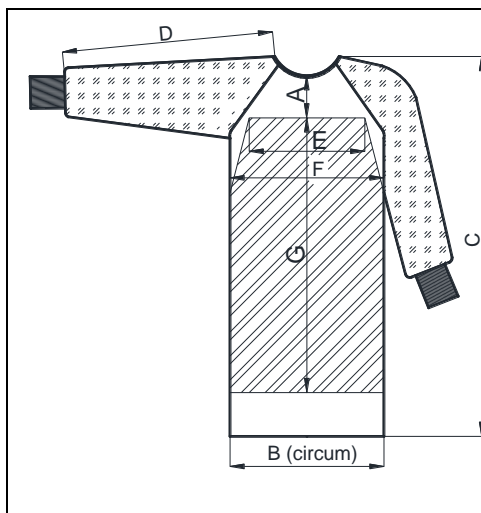
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5.2 Product dimensions Foliodress® Comfort perfect [cm]



Size	B	C	D
M	146	122	70
L	158	127	77
XL	170	147	88
XXL	180	155	88

5.3 Product dimensions Foliodress® Comfort special [cm]



Size	A	B	C	D	E	F	G
L	15	158	127	77	52	70	85
XL	15	170	147	88	55	70	105
XXL	15	180	155	88	55	70	105
XXLL	15	180	177	88	55	70	130

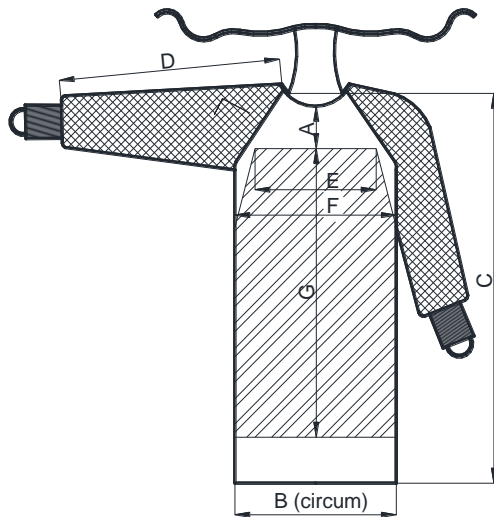


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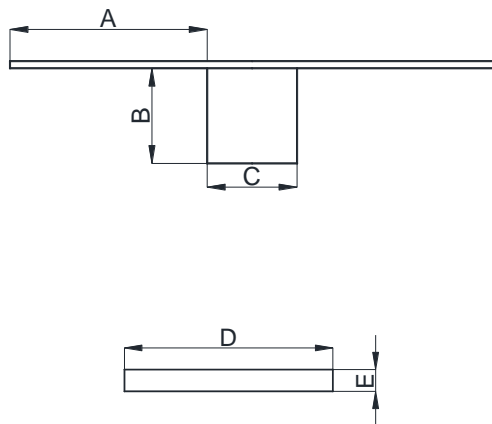
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5.4 Product dimensions Foliodress® Comfort B [cm]



Size	A	B	C	D	E	F	G
L	15	160	130	77	52	70	85
XL	15	170	150	88	55	70	105

Dimensions of Mask and Fingerloop



		size L [cm]	size XL [cm]
A	Mask: Tie Length	50	50
B	Mask: Height	28	28
C	Mask: Width	23	23
D	Fingerloop: Length	30	30
E	Fingerloop: Width	2	2



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5.5 Material properties (typical readings) – 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	4,4
Cleanliness - Microbial	EN ISO 11737-1	CFU/100cm ²	≤ 300	Sterile !
Cleanliness – Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	2,1
Linting	EN ISO 9073-10	log ₁₀ (lint count)	≤ 4,0	outside: 2,2 inside: 2,1
Resistance to liquid penetration	EN 20811	cm H ₂ O	≥ 20	37,0
Bursting strength - Dry	EN ISO 13938-1	kPa	≥ 40	163,0
Bursting strength - Wet	EN ISO 13938-1	kPa	≥ 40	161,0
Tensile strength - Dry	EN 29073-3	N	≥ 20	md: 65,3 cd: 33,9
Tensile strength - Wet	EN 29073-3	N	≥ 20	md: 68,8 cd: 35,4



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5.6 Material properties (typical readings): reinforced areas special (high performance)

Property	Test method	Unit	Requirements of EN 13795 (critical areas)	Test results Chest area	Test results Sleeves
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	6,0
Cleanliness - Microbial	EN ISO 11737-1	CFU/100cm ²	≤ 300	Sterile !	Sterile !
Cleanliness - Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	1,9	0,6
Linting	EN ISO 9073-10	log ₁₀ (lint count)	≤ 4,0	outside: 2,1 inside: 2,0	outside: 0,8 inside: 0,8
Resistance to liquid penetration	EN 20811	cm H ₂ O	≥ 100	> 200	> 200
Bursting strength - Dry	EN ISO 13938-1	kPa	≥ 40	259,0	216,0
Bursting strength - Wet	EN ISO 13938-1	kPa	≥ 40	251,0	199,0
Tensile strength - Dry	EN 29073-3	N	≥ 20	md: 115,0 cd: 94,0	md: 95,5 cd: 48,1
Tensile strength - Wet	EN 29073-3	N	≥ 20	md: 120,0 cd: 102,0	md: 95,7 cd: 41,5

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.



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6. 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: 5 years.

7. Packaging

Surgical gowns, individually sealed in sterile primary packing; packaged into polyethylene bags and 28 pieces in transport carton; transport carton acc. DIN, sealed with adhesive tapes, packaged onto europallet.

7.1. Foliodress®Comfort basic

Number of gowns / carton:
Size L 28
Size XL 28

7.2. Foliodress®Comfort Perfect

Number of gowns / carton
Size L 28
Size XL 28
Size XXL 28

7.3. Foliodress®Comfort Special

Number of gowns / carton
Size L 28
Size XL 28
Size XXL 28
Size XXLL 24



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7.4. Foliodress® Comfort Model B

Number of gowns / carton
Size L 28
Size XL 28

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

i. A.

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