



Foliodress® Comfort special classic, sterile



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

1. General Product Description

Foliodress® Comfort special classic 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; presentation well adapted to surgeries of long duration involving high quantities of fluid.

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

Foliodress® Comfort special classic OR-gowns correspond to the requirements of the European Standard EN 13795:2011. Foliodress® Comfort special classic 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 surgeries of long duration involving high quantities of fluid.

3. Presentations

Sizes: M, L, XL, XXL	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 special classic contains no natural rubber latex and is colophony free.	
- Nonwoven:	PP-Nonwoven (SMMMS), alcohol repellent and antistatic, alcohol repellancy (WSP 80.8(2005)) > Level 8
- Cuffs:	100 % Polyester
- Sewing thread:	100 % Polyester
- Combatape:	Tape with hooks and adhesive area of polypropylene, hot melt
- Additional protection against liquid penetration:	The front as well as the sleeves area of Foliodress® Comfort special classic are reinforced with a breathable 2-layer laminate ("AirActiv-reinforcement"). alcohol repellancy at reinforced front and sleeve area (WSP 80.8(2005)) > Level 8

5. Product requirements

5.1 Product dimensions Foliodress® Comfort special classic [cm]

	Size	A	B	C	D	E	F	G	H
	M	15	146	122	70	52	70	75	32
	L	15	158	127	77	52	70	85	40
	XL	15	170	147	88	55	70	105	40
	XXL	15	180	155	88	55	70	105	40



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5.2 Material properties (typical readings) – nonwoven (high performance/ less critical areas)

Property	Test method	Unit	Requirements of EN 13795	Test results
Resistance to microbial penetration - Dry	EN ISO 22612	CFU	≤ 300	0
Resistance to microbial penetration - Wet	EN ISO 22610	I _B	not required	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	≥ 10	37,0
Bursting strength - Dry	EN ISO 13938-1	kPa	≥40	163,0
Bursting strength - Wet	EN ISO 13938-1	kPa	not required	161,0
Tensile strength - Dry	EN 29073-3	N	≥ 20	md: 65,3 cd: 33,9
Tensile strength - Wet	EN 29073-3	N	not required	md: 68,8 cd: 35,4

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.



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5.3 Material properties (typical readings): reinforced areas (high performance/ critical areas)

Property	Test method	Unit	Requirements of EN 13795	Test results Chest / sleeves area
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/ 100cm ²	≤ 300	Sterile !
Cleanliness – Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	1,8
Linting	EN ISO 9073-10	log ₁₀ (lint count)	≤ 4,0	outside: 1,9 inside: 1,9
Resistance to liquid penetration	EN 20811	cm H ₂ O	≥ 100	151,0
Bursting strength - Dry	EN ISO 13938-1	kPa	≥ 40	247,0
Bursting strength - Wet	EN ISO 13938-1	kPa	≥ 40	230,0
Tensile strength - Dry	EN 29073-3	N	≥ 20	md: 122,0 cd: 66,5
Tensile strength - Wet	EN 29073-3	N	≥ 20	md: 123,0 cd: 68,2

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. .

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:

The shelf life is 5 years.



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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.

Date: 2015-01-09

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

i. A.

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