

		<h1>Technical Data Sheet</h1>
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Foliodrape® COMFORT Stockinets (rolled)		Spec.-No.:	D 6.5417a
		Department:	CMO-DOE
		Date:	2013-01-23

1. General Product Description

Foliodrape® COMFORT stockinets (rolled) are made of 2-layer non-woven/film material; the top layer is abrasion-resistant and impermeable to moisture and bacteria; the inner side is soft and kind to the skin.

Foliodrape® COMFORT carries the CE-mark according to EU directive 93/42/EEG for medical devices. The product is classified as a class I medical device.

A conformity assessment has been performed for Foliodrape® COMFORT and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Foliodrape® COMFORT, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Foliodrape® COMFORT stockinets is a disposable product for sterile covering of legs or arms.

3. Product Characteristics

composition:	Non-woven with co-extruded film on one side, 70g/m ² ; latex-free
nonwoven :	Polypropylene fibres with hydrophilic finishing
film:	Polyethylene
sterilization	with ethylene oxide gas

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4. Product Requirements

The material of the Foliodrape® COMFORT stockinet corresponds to all requirements of European standard EN 13795:2011 for the highest performance level “High performance, critical area”

Characteristic:	Unit	Requirements according EN 13795 for “High Performance critical product area”	Foliodrape® Comfort stockinet (typical values)¹⁾
Resistance to microbial penetration – dry in accordance with EN ISO 22612	CFU	Not required	Not required
Resistance to microbial penetration - wet in accordance with EN ISO 22610	I _B	6,0	6,0 (no penetration)
Cleanliness – microbial in accordance with EN ISO 11737-1	CFU/ 100cm ²	≤ 300	sterile in accordance with EN 556
Cleanliness – particulate matter in accordance with EN ISO 9073-10	IPM	≤ 3,5	< 3,0
Linting in accordance with EN ISO 9073-10	Log ₁₀ (lint count)	≤ 4,0	< 3,5
Resistance to liquid penetration in accordance with EN 20811	cm (H ₂ O)	≥ 100	≥150 ²⁾
Bursting strength – dry in accordance with EN ISO 13938-1	kPa	≥ 40	>100
Bursting strength – wet in accordance with EN ISO 13938-1	kPa	≥ 40	> 50
Tensile strength – dry in accordance with EN 29073-3	[N/50 mm]	≥ 20	cross direction: > 50 (machine direction: >60)
Tensile strength – wet in accordance with EN 29073-3	[N/50 mm]	≥ 20	cross direction: > 50 (machine direction: >60)

¹⁾ Test report from independent Testing-Institute is available on request

²⁾ measured without use of supporting tissue

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5. Presentations

Sterile, single sealed or as component in several sets

Single sealed products	Size (content)	Article no.
Stockinets (rolled) (in crepe wrap)	25 x 80 cm (30 pieces)	258 982/2
	35 x 80 cm (25 pieces)	258 981/2
	35 x 120 cm (20 pieces)	258 980/2
	25 x 80 cm + OP Tape (28 pieces)	258 209/4


6. Labelling

Lot-No. with 9-digit code:

e.g.:

LOT	2	XXX	38	YYY
	year	internal code	week of production	internal code

Expiry date:

e.g.  2017 12
year month

Shelf life: 5 years

The product will be sterile during this period as long as the packaging is not damaged and the storage conditions are kept.

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7. Packaging

Foliodrape®Comfort stockinet (rolled) as a component in a set or as a single product, sealed into sterile packaging (peeling pouch) according to EN ISO 11607 and EN 868. The peel pouch is packed into folding box and transport carton, sealed with adhesive tapes and stored on euro-pallet.

Date: 2013-01-23

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i. A.



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