


		<h1>Technical Data Sheet</h1>
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Foliodrape® COMFORT Arm Cover, sterile		Spec.-No.:	D 6.5402
		Department:	CMO-DOE
		Date:	2013-01-23

1. General Product Description

Foliodrape® COMFORT arm cover is made of special, breathable 3-layer-laminate; elastic cuffs; impermeable to moisture and bacteria; abrasion-resistant and low linting.

Foliodrape® COMFORT arm cover 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 Foliodrape® COMFORT arm cover and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

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

Foliodrape® COMFORT arm cover corresponds to the requirements of the European Standard EN 13795. Foliodrape® COMFORT arm cover is classified as high- performance product (critical area).

2. Application / Indication


For single use in surgical procedures only; for sterile covering of surgical gown sleeves in case of high quantities of fluid to reduce the risk of contamination.

3. Product Characteristics

<u>Material:</u>	
basis material:	laminate of nonwoven – film (weight 65 g/m²)
nonwoven:	polypropylene – nonwoven
film:	PE – film, breathable
elastic cuffs:	100% Polyester or 50% Polyester / 50% Polyamid
elastics:	latex free
sewing thread:	Polyester
Foliodrape® COMFORT arm cover contains no natural rubber!	

4. Dimensions

- length:	approx. 50 cm
- width top:	approx. 50 cm
- width cuffs:	approx. 30 cm

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5. Product Requirements

Foliodrape® COMFORT Arm Cover corresponds to all requirements of European standard EN 13795 for the highest performance level "High performance, critical area".

For Details see Technical Data sheet of the Foliodress Comfort special (reinforced areas special; high performance D 9.5111).base material

All data refer to sterile products!


6. Labelling

Lot-No. with 9-digit code:

e.g.: 9XXX38YYY

LOT	9	XXX	38	YYY
	year of production	for internal purposes only	week of production	for internal purposes only

Expiry date:

e.g.  2014 – 01
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.

7. Packaging

Foliodrape® COMFORT Arm Cover is 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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