

Foliodrape® COMFORT Extremity Drapes		Spec.-No.:	D 6.5905a
		Department:	CMO-DOE
		Date:	2013-01-25

1. General Product Description

Foliodrape® COMFORT Extremity Drapes is for orthopaedic and accident surgery. The Comfort Extremity Drapes is made of soft, three-layer material; with elastic fenestration in the centre of the sheet and velcro fastener for securing suction tubes; impermeable to moisture and bacteria; abrasion-resistant and low linting.

Foliodrape® COMFORT carries the CE-mark according to EU directive 93/42/EWG 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 extremity drapes is a disposable product for sterile draping of the patient.

3. Presentations

- Art.-No. 254 038** **Foliodrape® COMFORT extremity drape (ø fenestration 3 cm)**
sterile, 9 pieces per dispenser, 2 dispenser per transport carton
- Art.-No. 254 332** **Foliodrape® COMFORT extremity drape (ø fenestration 7 x 5 cm)**
sterile, 9 pieces per dispenser, 1 dispenser per transport carton
- Art.-No. 254 340** **Foliodrape® COMFORT extremity drape (ø fenestration 10 x 7 cm)**
sterile, 7 pieces per dispenser, 1 dispenser per transport carton

4. Product Characteristics

Composition:	three-layer laminate of nonwoven-film-nonwoven
nonwoven:	viscose – nonwoven, chemical bonded
adhesive:	dispersion adhesive or hotmelt
film:	polyethylene – film, mat
PP-nonwoven:	polypropylene - nonwoven -SMS
elastic film:	polyethylene film, green mat (EVA- Copolymer)
Velcro fastener:	
hook:	polyamide / polyurethane woven; backing side with synthetic resin
velour:	polyamide / polyurethane woven
sterilization:	with ethylene oxide

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5. Product Requirements

Foliodrape® COMFORT corresponds to all requirements of European standard for surgical drapes EN 13795, for the highest performance level “High performance, critical area”.

For details see Technical Data sheet of the base material (D 6.5030).

6. Labelling

Lot-No. with 9-digit code:

e.g.:

LOT	9	XXX	38	YYY
	year	internal code	week of production	internal code

Expiry date:

e.g.  2014 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.

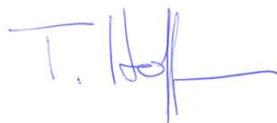
7. Packaging

Foliodrape® COMFORT extremity drape is wrapped into crepe paper, 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: 2013-01-25

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i. A.



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