

Foliodrape® COMFORT Under-gluteal drape,		Spec.-No.:	P6.5905h
		Department:	CMO-DOE
		Date:	2013-03-18

1. General Product Description

Drape made of soft, three-layer material; impermeable to moisture and bacteria; well comfortable; e.g. for usage as sterile under-gluteal drape in obstetrics.

Foliodrape® COMFORT under-gluteal drape 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 under-gluteal drape, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

For use as sterile under-gluteal drape, e.g. in obstetrics.

3. Presentation

Sterile

	Size (Content per dispenser)	Dispenser per box	Article no.
Under-gluteal Drape	100 x 140 cm (20 pieces)	2	251 010

4. Product Characteristics

Composition:	Three-layer nonwoven-film-laminate
Nonwoven (outside):	Viscose, colour: aqua
Film:	Polyethylene-film, colour: aqua
Nonwoven (inner side)	Polypropylene SMS, colour white
Sterilization:	With ethylene oxide gas

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5. Product Requirements (typical values)

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 COMFORT 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 01
 year month

Shelf life: 5 years


7. Packaging

Foliodrape® COMFORT under-gluteal drape 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.

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

i. A.



Dr. Thomas Hoffmann