


<b>Foliodrape® COMFORT</b> <b>Laparotomy Drape</b> <b>Art. No. 254 432</b>		Spec.-No.:	D 6.5905b
		Department:	CMO-DOE
		Date:	2013-01-25

## 1. General Product Description

Foliodrape® COMFORT Laparotomy Drape made of soft, three-layer material; with adhesive area and velcro fastener for securing suction tubes and cautery cables; 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 Laparotomy Drape is a disposable product for sterile draping of the patient.

## 3. Presentations

**Art. No. 254 432**

**Foliodrape® COMFORT Laparotomy Drape, 260 x 320 cm**  
sterile, 8 pieces per dispenser, 1 dispenser per transport carton

## 4. Product Characteristics

<u>Material:</u>	
basis material:	laminate of nonwoven – film – nonwoven
nonwoven:	viscose – nonwoven, chemical bonded
adhesive:	dispersions adhesive and hotmelt, based of vinyl acetate – Copolymer
film:	Polyethylene – film, mat
PP- nonwoven:	Polypropylene – nonwoven, SMS
adhesive tape:	Polyester film, double coated with synthetic rubber resin latex - free and silicone paper
hook:	Polyamide / Polyurethane woven; backing side with synthetic rubber 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.:      **9XXX38YYY**

<b>LOT</b>	9	XXX	38	YYY
	year of production	for internal purpose 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.

		<h1>Technical Data Sheet</h1>
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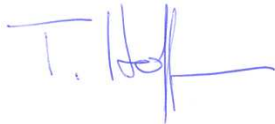
**7. Packaging**

Foliodrape® COMFORT Laparotomy 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.



Dr. Thomas Hoffmann