



**Foliodrape® COMFORT**  
**Adhesive Chest Drapes**  
**Art.-No. 253 348**



Spec.-No.:	D 6.5905f
Department:	CMO-DOE
Date:	2013-01-25

### 1. General Product Description

*Foliodrape® COMFORT adhesive chest drapes* for thoracotomy is made of soft, three-layer material; with adhesive area around the U-shaped slit for rapid positioning around the operation site, impermeable to moisture and bacteria; abrasion-resistant and low linting.

*Foliodrape® COMFORT adhesive chest drapes* 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 adhesive chest drapes*, therefore, is ensured if the product is used in line with the intended purpose.

### 2. Application / Indication

*Foliodrape® COMFORT adhesive chest drapes* is a disposable product for sterile draping of the patient.


### 3. Presentations

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***Foliodrape® COMFORT adhesive chest drape 260 x 325 cm***  
sterile, 5 pieces per dispenser, 1 dispenser per transport carton

### 4. Product Characteristics

Material:	
basis material:	laminate of nonwoven – film – nonwoven
nonwoven:	viscose – nonwoven, chemical bonded
adhesive:	dispersions adhesive, based of vinyl acetate – Copolymer
film:	Polyethylene – film, mat
PP- nonwoven:	Polypropylene – nonwoven, SMS
adhesive tape:	Polypropylene film, double coated with synthetic rubber latex-free resin and silicone paper
incisions film:	Polyurethane film, transparent, with medical acrylate hotmelt latex-free and silicone paper
hook:	Polyamide / Polyurethane woven; backing side with synthetic rubber resin
velour:	Polyamide / Polyurethane woven

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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**

LOT	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.

## 7. Packaging

*Foliodrape® COMFORT adhesive chest drapes 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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