



## Foliodrape® COMFORT Urology Set I (Art. No. 257 133)



Spec.-no.: D 6.5321a

Department: CMO-DOE

Date: 2013-01-31

### 1. General Product Description

Foliodrape® COMFORT Urology Set I for sterile draping in urethroplasty, for extraction of ureteral stones, in surgical cystoscopic procedures as well as in the excision of bladder papillomas.

The Foliodrape® COMFORT Urology Set I carries the CE-mark according to EU directive 93/42/EWG for medical devices and is classified as class I medical devices.

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 Urology Set I, therefore is ensured if the product is used in line with the intended purpose.

### 2. Application / Indication

Foliodrape® COMFORT Urology Set I is a disposable product for sterile draping of the patient and the theatre equipment.

### 3. Presentations:

<b>Art. No. 257 133</b>	<b>Foliodrape® Comfort Urology Set I</b>
	sterile, 7 Sets per dispenser, 1 dispenser per transport carton
	Dimensions of dispenser: 565 x 370 x 295 mm (L x W x H)
	Dimensions of transport carton: 585 x 385 x 315 mm (L x W x H)

### 4. Product characteristics

<b>Content:</b>	1 table cover 140 x 190 cm
	1 urology drape sheet 150 x 200 with suprapubic adhesive aperture, with genital adhesive aperture, fingerstall and fluid collection bag
	1 adhesive tape 10 x 50 cm
	4 cellulose towels 33 x 33 cm
<b>Sterilization:</b>	With ethylene oxide gas

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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) and table cover (D 6.5410a).*

**6. Labelling** Lot no. with 9-digit code:

e.g.: 9XXX38YYY

<b>LOT</b>	<b>9</b>	<b>XXX</b>	<b>38</b>	<b>YYY</b>
	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.

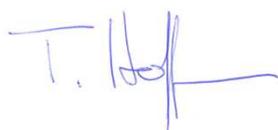
**7. Packaging**

Foliodrape® COMFORT Urology Set I 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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i. A.



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