

Foliodrape® COMFORT, Gynaecology- Cystoscopy Set II (Art. No. 257 612)		Spec.-No.:	D 6.5303k
		Department:	CMO-DOE
		Date:	2013-01-23

1. General Product Description

Foliodrape® COMFORT Gynaecology- Cystoscopy- Set II for gynaecological and urological procedures.

The *Foliodrape® COMFORT Gynaecology- Cystoscopy- Set II* carries the CE-mark according to EU directive 93/42/EEG for medical devices and is classified as class I sterile medical devices. A conformity assessment has been performed for *Foliodrape® COMFORT Gynaecology- Cystoscopy- Set II* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of *Foliodrape® COMFORT Gynaecology- Cystoscopy- Set II*, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Foliodrape® COMFORT Gynaecology- Cystoscopy- Set II is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 257 612	Foliodrape® COMFORT Gynaecology- Cystoscopy- Set II
	sterile, 5 Sets per dispenser, 2 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

Content:	1 table cover 100 x 150 cm
	1 Gynaecology- Cystoscopy drape 75 x 200 cm with aperture 8 x 12 cm (self adhesive)
	2 Leggings 50 x 110 cm
	4 Cellulose towels 33 x 33 cm
	Sterilization With ethylene oxide gas according to DIN EN ISO 11135-1
Self adhesives:	Skin-friendly synthetic rubber, latex free and colophony free

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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

LOT	9	XXX	38	YYY
	Year of production	For internal purpose only	Week of production	For internal purpose 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 Gynaecology- Cystoscopy- Set II 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.

Date: 2013-01-23

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i. A.



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