

		Technical Data Sheet
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Foliodrape® Protect, Gynaecology-/Cystoscopy Set (Art. No. 938 916)		Spec.-No.:	D 6.1002j
		Department:	CMO-DOE
		Date:	2014-11-17

1. General Product Description

Foliodrape® Protect Gynaecology-/Cystoscopy Set for gynaecologic and urologic surgery in lithotomy position. Preferred for interventions like conisation, cystoscopy, urethroscopy, vaginal cysts etc.

The *Foliodrape® Protect Gynaecology-/Cystoscopy Set* carries the CE-mark according to EU directive 93/42/EEG for medical devices and is classified as class I medical devices.

A conformity assessment has been performed for *Foliodrape® Protect* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

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


2. Application / Indication

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

3. Presentations

Art. No. 938 916	<i>Foliodrape® Protect Gynaecology-/Cystoscopy Set</i>
	sterile, 6 Sets per dispenser, 2 dispenser per transport carton
	Dimensions of dispenser: 275 x 374 x 234 mm (L x W x H)
	Dimensions of transport carton: 590 x 390 x 250 mm (L x W x H)

4. Product Characteristics

Content:	1 table cover 150 x 100 cm (2-layer material)
	1 Gynaecology-/Cystoscopy drape sheet 75x200 cm with fenestration in "diamond" shape 12 x 8 cm
	2 leggings 120 x 75 cm (made of 2-layer material)
Sterilization:	With ethylene oxide gas according to EN 556-1 and EN 11135-1

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5. Product Requirements

Foliodrape® Protect 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 6.1005a).


6. Labelling

Lot-No. with 9-digit code:

e.g.: 5023XXXXX

LOT	5	023	XXXXX
	year of production	serial production order	for internal purposes only

Expiry date:

e.g.  2019 – 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® Gynaecology-/Cystoscopy Set is packed into crepe paper and 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: 2014-11-17

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i. A.



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