


		Technical Data Sheet
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Foliodrape® Protect, Caesarean Section Set V with fluid collection bag (Art. No. 938 918)		Spec.-No.:	D 6.1002k
		Department:	CMO-DOE
		Date:	2014-11-17

1. General Product Description

Foliodrape® Protect Caesarean Section Set V with fluid collection bag for gynaecological abdominal surgeries, e.g. Section caesarean.

The *Foliodrape® Protect Caesarean Section Set V with fluid collection bag* 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® Protect Caesarean Section Set V with fluid collection bag* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of *Foliodrape® Protect Caesarean Section Set V with fluid collection bag*, therefore, is ensured if the product is used in line with the intended purpose.

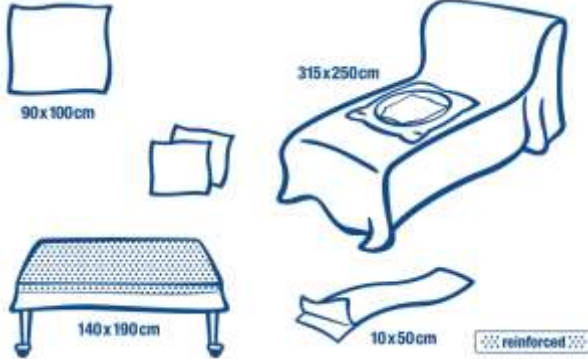
2. Application / Indication

Foliodrape® Protect Caesarean Section Set V with fluid collection bag is a disposable product for sterile draping of the patient and the theatre equipment.


3. Presentations

Art. No. 938 918	<i>Foliodrape® Protect Caesarean Section Set V with fluid collection bag</i>
	sterile, 5 Sets per dispenser, 1 dispenser per transport carton
	Dimensions of dispenser: 545 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 reinforced table cover 140 x 190 cm
	1 caesarean section drape 250 x 315 cm with one fenestration (19 x 29 cm "kidney" shape) and fluid collection bag
	1 baby drape 90 x 100 cm
	1 adhesive tape 10 x 50 cm
	2 cellulose towels 30 x 33 cm
Sterilization:	With ethylene oxide gas according to EN 556-1 and EN 11135-1
Self adhesives:	Skin-friendly synthetic rubber, latex free and colophony free

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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) and back table cover (D 6.1005d).


6. Labelling

Lot-No. with 9-digit code:

e.g.: 8023XXXXX

LOT	8	023	XXXXX
	year of production	serial production order	for internal use

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® Protect Caesarean section Set V with fluid collection is wrapped in 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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