		Technical Data Sheet	
Foliodrape® Equipment Cover (Art. No. 938 846)		Spec.-No.:	D 6.1010b
		Department:	CMO-DOE
		Date:	2015-01-22

1. General Product Description

Foliodrape® Equipment Cover as a sterile cover for medical apparatus.

Foliodrape® Equipment Cover 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®* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use and effectiveness of *Foliodrape® Equipment Cover*, therefore, is ensured if the product is used in line with the intended purpose.


2. Application / Indication

Foliodrape® Equipment Cover is a disposable product for sterile draping of the theatre equipment.

3. Presentations

Art. No. 938 846	<i>Foliodrape® Equipment Cover</i>
	sterile, 25 drapes per dispenser, 2 dispenser per transport carton
	Dimensions of dispenser: 374 x 275 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: 	transparent, resistant polyethylene film with elastic band, latex-free
Sterilization:	With ethylene oxide gas according to EN 556-1 and EN 11135-1

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5. Labelling

Lot-No. with 9-digit code:

e.g.: 4023XXXXX

LOT	4	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.

6. Packaging

Foliodrape® Equipment Cover 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: 2015-01-22

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