



# Technical Data Sheet

**Foliodrape® Protect,  
Gynaecology Set I  
(Art. No. 938 745)**



Spec.-No.:	D 6.1002I
Department:	CMO-DOE
Date:	2014-11-17

## 1. General Product Description

*Foliodrape® Protect Gynaecology Set I* preferred for interventions like vaginal uterus extirpation or marsupialization of vaginal cysts and Bartholin's glands.

The *Foliodrape® Protect Gynaecology Set I* 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 Set I*, therefore, is ensured if the product is used in line with the intended purpose.

## 2. Application / Indication

*Foliodrape® Protect Gynaecology Set I* is a disposable product for sterile draping of the patient and the theatre equipment.

## 3. Presentations

<b>Art. No. 938 745</b>	<b><i>Foliodrape® Protect Gynaecology Set I</i></b>
	sterile, 10 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

<b>Content:</b>	
	1 fenestrated drape sheet 240 x 255 cm (fenestration 7 x 10 cm) with self-adhesive zone around the fenestration
	4 cellulose towels 30 x 33 cm
<b>Sterilization:</b>	With ethylene oxide gas according to EN 556-1 and EN 11135-1
<b>Self adhesives:</b>	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).*

## 6. Labelling

Lot-No. with 9-digit code:

e.g.: 5023XXXXX

LOT	5	023	XXXXX
	year of production	serial product order	for internal proposes 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® Protect Gynaecology Set I* 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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