



Foliodrape® Protect, Gynaecology Set with fluid collection bag (Art. No. 938 903)



Spec.-No.:	D 6.1002b
Department:	CMO-DOE
Date:	2014-12-01

1. General Product Description

Foliodrape® Protect Gynaecology Set with fluid collection bag for all trans- and intravaginal surgeries, e.g. vaginal and pelvis floor plastic surgeries, vaginal hysterectomy.

The *Foliodrape® Protect Gynaecology Set with fluid collection bag* carries the CE-mark according to EU directive 93/42/EWG for medical devices and is classified as class I sterile medical devices. A conformity assessment has been performed for *Foliodrape® Protect Gynaecology Set 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 Gynaecology Set with fluid collection bag*, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

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

3. Presentations

Art. No. 938 903	Foliodrape® Protect Gynaecology Set with fluid collection bag
	sterile, 6 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

<p>Content:</p>	1 reinforced table cover 140 x 190 cm
	1 gynaecology drape 250 x 290 cm with oval fenestration (9 x 12 cm), a fluid collection bag and integrated leggings
	1 drape 75 x 90 cm
	1 adhesive tape 10 x 50 cm
	1 cellulose towel 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



Technical Data Sheet

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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 Gynaecology Set 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: 2014-12-01

PAUL HARTMANN AG
Development OTM & Exam. Gloves (CMO-DOE)

i. A.

Dr. Evelyn Hartmann