

		<h1>Technical Data Sheet</h1>
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<b>Foliodrape® Protect, Gynaecology Set (Art. No. 278 009)</b>		Spec.-No.:	D 6.5350o
		Department:	CMO-DOE
		Date:	2013-01-28

1. General Product Description

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

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

2. Application / Indication


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

3. Presentations

<b>Art. No. 278 009</b>	<b>Foliodrape® Protect Gynaecology Set</b>
	sterile, 7 Sets per dispenser, 2 dispenser per transport carton
	Dimensions of dispenser: 370 x 275 x 250 mm (L x W x H)
	Dimensions of transport carton: 585 x 390 x 270 mm (L x W x H)

4. Product Characteristics

<b>Content:</b>	1 table cover 150 x 100 cm
	1 fenestrated drape sheet 100 x 200 cm (fenestration 7 x 10 cm) with self-adhesive zone around the fenestration
	2 leggings 75 x 120 cm made of Polyethylene film
	2 cellulose towels 33 x 33 cm
<b>Sterilization:</b>	With ethylene oxide gas

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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 table cover (D6.1005d).*

6. Labelling

Lot-No. with 9-digit code:

e.g.: 5XXX38YYY

LOT	5	XXX	38	YYY
	year of production	for internal purposes only	week of production	for internal purposes only

Expiry date:

e.g. ⌚ 2011 – 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* is 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: 2013-01-28

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