

		<h1>Technical Data Sheet</h1>
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Foliodrape® Protect Plus, Under-Gluteal Drape reinforced (Art. No. 938 829)		Spec.-No.:	D 6.1009e
		Department:	CMO-DOE
		Date:	2014-06-01

1. General Product Description

Foliodrape® Protect Plus Under-Gluteal Drape reinforced, e.g. for usage as sterile under-gluteal drape in obstetrics.

Foliodrape® Protect Plus Under-Gluteal Drape reinforced 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 Plus* 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® Protect Plus Under-Gluteal Drape reinforced*, therefore, is ensured if the product is used in line with the intended purpose.

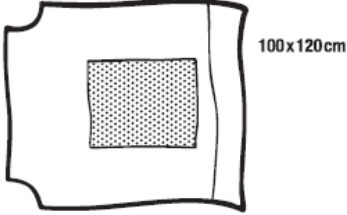
2. Application / Indication

Foliodrape® Protect Plus Rhinoplast/Septum reinforced is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 938 829	<i>Foliodrape® Protect Plus Under-Gluteal Drape reinforced</i>
	sterile, 22 drapes per dispenser, 2 dispenser per transport carton
	Dimensions of dispenser: 275 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 under-gluteal drape reinforced 100 x 120 cm with cuff
Sterilization:	With ethylene oxide gas according to DIN EN ISO 11135-1
Self adhesives:	Skin-friendly synthetic rubber, latex free and colophony free

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5. Product Requirements

Foliodrape® Protect Plus 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, D 6.1005b).

6. Labelling

Lot-No. with 9-digit code:

e.g.: 1023XXXXX

LOT	1	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 Plus Under-Gluteal Drape reinforced 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: 2014-06-01

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i. A.



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