
		Technical Data Sheet
--	--	----------------------

Foliodrape® Protect, Minor surgery set (Art. No. 938 914)		Spec.-no.:	D6.1010I
		Department:	CMO-DOE
		Date:	2016-01-26

1. General Product Description

Foliodrape® Protect Minor surgery Set is for small surgeries.

The Foliodrape® Protect Minor surgery set carries the CE-mark according to EU directive 93/42/EWG 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 Minor surgery set, therefore, is ensured if the product is used in line with the intended purpose.

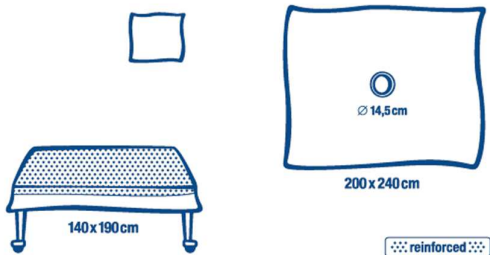
2. Application / Indication



Foliodrape® Minor surgery set is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations:

Art. Nr. 938 914	<i>Foliodrape® Protect Minor surgery set</i>
	sterile, 10 Sets per dispenser, 1 dispenser per transport carton
	Dimension of dispenser: 545 x 374 x 234 mm (L x W x H)
	Dimension of transport carton: 590 x 390 x 250 mm (L x W x H)

4. Product characteristics

Content: 	1 table cover reinforced 140 x 190 cm
	1 fenestrated drape 200 x 240 cm (fenestration Ø 14,5 cm, with self-adhesive zone around)
	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		
Foliodrape® Protect, Minor surgery set (Art. No. 938 914)			Spec.-no.:	D6.1010I
			Department:	CMO-DOE
			Date:	2016-01-26

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 6.1005), and table cover (D 6.1005d).

6. Labelling Lot no. with 9-digit code:

e.g.: 6023XXXXX

LOT	6	023	XXXXX
	year of production	Serial production order	for internal purposes only

Expiry date:

e.g.  2021 – 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 Minor surgery set is wrapped into sterile 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: 2016-01-26

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

i. A.



Dr. Evelyn Hartmann