

		<h1>Technical Data Sheet</h1>
--	--	-------------------------------

Foliodrape® Epidural Drape, transparent (Art. No. 938 821)	Spec.-No.:	D 6.1010d
	Department:	CMO-DOE
	Date:	2017-06-06

1. General Product Description

Foliodrape® Epidural Drape, transparent for sterile draping of the patient for pre-operative epidural, peridural and lumbar anaesthesia.

Foliodrape® Epidural Drape, transparent 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®* 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® Epidural Drape, transparent*, therefore, is ensured if the product is used in line with the intended purpose.

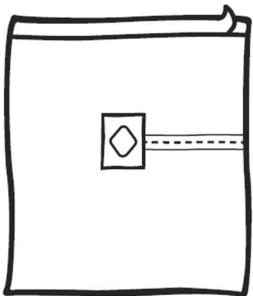
2. Application / Indication

Foliodrape® Epidural Drape, transparent is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 938 821	<i>Foliodrape® Epidural Drape, transparent</i>
	sterile, 40 drapes per dispenser, 2 dispenser per transport carton
	Dimensions of dispenser: 374 x 275 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>  <p>90x120cm</p>	<p>1 epidural drape, transparent 90 x 120 cm with diamond shaped aperture 10 x 12 cm, a self-adhesive area around the fenestration and at the upper edge of the drape and a perforation for an easier and safe removal of the drape after the intervention</p>
<p>Sterilization:</p>	<p>With ethylene oxide gas according to EN 556-1 and EN 11135-1</p>
<p>Self adhesives:</p>	<p>Skin-friendly synthetic rubber, latex free and colophony free</p>

Foliodrape® Epidural Drape, transparent (Art. No. 938 821)		Spec.-No.:	D 6.1010d
		Department:	CMO-DOE
		Date:	2017-06-06

5. Product Requirements

Foliodrape® Epidural Drape, transparent corresponds to all requirements of European standard EN 13795: 2011 for the highest performance level “High performance, critical area”.

For Details see Technical Data sheet of the base material (D 6.1011f).

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® Epidural Drape, transparent 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: 2017-06-06

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

i. A.



Dr. Leonie Lindner