


		Technical Data Sheet
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Foliodrape® COMFORT Head Set (Art. No. 257 586)		Spec.-no.:	D 6.5338b
		Department:	CMO-DOE
		Date:	2013-03-15

1. General Product Description

Foliodrape® COMFORT Head Set for sterile draping in ear, nose, throat, neck and eye surgeries, e.g. septo-rhinoplasty, face lift and tonsillectomy.

The Foliodrape® COMFORT Head 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® COMFORT and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Foliodrape® COMFORT Head Set therefore is ensured if the product is used in line with the intended purpose.

2. Application / Indication


Foliodrape® COMFORT Head Set is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations:

Art. No. 257 586	Foliodrape® Comfort Head Set
	sterile, 6 Sets per dispenser, 1 dispenser per transport carton
	Dimensions of dispenser: 565 x 370 x 295 mm (L x W x H)
	Dimensions of transport carton: 585 x 385 x 315 mm (L x W x H)

4. Product characteristics

Content:	1 table cover 140 x 190 cm
	1 self-adhesive drape sheet 170 x 175 cm
	1 turban drape 150 x 175 x 100 x 110 cm
	1 adhesive tape 10 x 50 cm
	1 mayo Stand Cover 80 x 145 cm
Sterilization:	With ethylene oxide gas

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5. Product requirements:

Foliodrape® COMFORT 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 COMFORT base material (D 6.5030), the mayo stand cover (D6.5403) and table cover (D 6.5410a).

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

e.g.: **9XXX38YYY**

LOT	9	XXX	38	YYY
	year of production	for internal purpose only	week of production	for internal purposes only

Expiry date:

e.g. ⌚ 2014 – 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® COMFORT Head 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: 2013-03-15

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