

		Technical Data Sheet		
Foliodrape® COMFORT Multipurpose Equipment Covers			Spec.-no.:	D 6.5411
			Department:	CMO-DOE
			Date:	2013-02-04

1. General Product Description

Foliodrape® COMFORT multipurpose equipment covers are made from transparent PE-film and an elastic rubber band.

Foliodrape® COMFORT multipurpose equipment covers carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class I* medical device. A conformity assessment has been performed for Foliodrape® COMFORT multipurpose equipment covers and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of Foliodrape® COMFORT multipurpose equipment covers, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / indication

Foliodrape® COMFORT multipurpose equipment covers is a disposable product for sterile draping of theatre equipment like computer monitor etc.

3. Presentations

Art. No. 258 096	<i>Foliodrape® Comfort Multipurpose Equipment Cover (50x100cm)</i>
	sterile, 30 pieces per dispenser, 2 dispenser per transport carton
Art. No. 258 095	<i>Foliodrape® Comfort Multipurpose Equipment Cover (85x150cm)</i>
	sterile, 20 pieces per dispenser, 2 dispensers per transport carton
	Dimensions of dispenser: 295 x 138 x 365 mm (L x W x H)
	Dimensions of transport carton: 577 x 377 x 304 mm (L x W x H)

4. Product characteristics

Composition:	PE-film, transparent Elastic rubber band
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5. Product requirements:

Film thickness:	60 µm
Dimensions:	50x100 cm 85x150 cm


6. Labelling

Lot no. with 9-digit code:

e.g.: **2XXX38YYY**

LOT	2	XXX	38	YYY
	year of production	for internal purpose only	week of production	for internal purposes only

Expiry date:

e.g.  2017 – 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 multipurpose equipment covers is wrapped into sterile crepe paper, 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: 2013-02-04

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