

Foliodrape® COMFORT Armrest Protection Sheath		Spec.-No.:	D 6.5412
		Department:	CMO-DOE
		Date:	2013-01-25

1. General Product Description

Foliodrape® COMFORT Armrest Protection Sheath made of soft, three-layer material; with adhesive strip; impermeable to moisture and bacteria; abrasion-resistant and low linting.

Foliodrape® COMFORT carries the CE-mark according to EU directive 93/42/EEG for medical devices. The product is classified as a class I medical device.

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, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Foliodrape® COMFORT Armrest Protection Sheath is a disposable product for sterile covering of armrests.

3. Presentations

Art. No. 258 250 **Foliodrape® COMFORT Armrest Protection Sheath, 25 x 80 cm, paired packed**
sterile, 25 x 2 pieces per dispenser, 2 dispenser per transport carton

Art. No. 258 963 **Foliodrape® COMFORT Armrest Protection Sheath, 35 x 75 cm, paired packed**
sterile, 12 x 2 pieces per dispenser, 4 dispenser per transport carton

4. Product Characteristics

<u>Material:</u>	
basis material:	laminate of nonwoven – film – nonwoven
nonwoven:	viscose – nonwoven, chemical bonded
adhesive:	dispersions adhesive, based of vinyl acetate – Copolymer
film:	Polyethylene – film, mat
PP- nonwoven:	Polypropylene – nonwoven, spunbonded
adhesive tape:	Polypropylene film with adhesive based of synthetic rubber and silicone paper
sewing thread:	Polyester
sterilization:	with ethylene oxide

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5. Product Requirements

Foliodrape® COMFORT Armrest Protection Sheath corresponds to all requirements of European standard for surgical drapes EN 13795:2011, for the highest performance level “High performance, critical area”

For Details see Technical Data sheet of the base material (D 6.5030).

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.

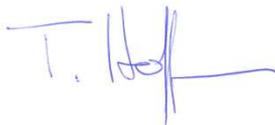
7. Packaging

Foliodrape® COMFORT Armrest Protection Sheath 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: 2013-01-25

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i. A.



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