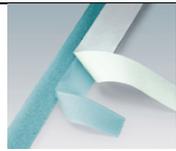


Foliodrape® COMFORT Velcro Fastener		Spec.-No.:	D 6.5408
		Department:	CMO-DOE
		Date:	2013-02-04

1. General Product Description

Foliodrape® COMFORT Velcro Fastener consists of two piece Velcro fastener with self - adhesive backing.

Foliodrape® COMFORT Velcro Fastener 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 Velcro Fastener and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of Foliodrape® COMFORT Velcro Fastener, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Foliodrape® COMFORT Velcro Fastener is a disposable product for securing video cables, tubes, cautery cables etc.

3. Presentations

Art. No. 258 280	Foliodrape® Comfort Velcro Fastener (2x23cm)
	sterile, in 3- layer packaging 200 pieces per dispenser, 4 dispenser 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

material:	
basis material:	Polyamid fabric Polyacrylat backing Pressure sensitive adhesive on basis of synthetic rubber, latex- free
backing paper:	Silicone paper

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5. Product Requirements

length:	23 cm
width:	2 cm
sterilization:	with ethylene oxide

6. Labelling

Lot-No. with 9-digit code:

e.g.: 9XXX38YYY

LOT	9	XXX	38	YYY
	year of production	for internal purposes 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 Velcro Fastener 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: 2013-02-04

PAUL HARTMANN AG
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i. A.



Dr. Thomas Hoffmann