

Foliodrape® Velcro Fastener (Art. No. 938 858)	Spec.-No.:	D 6.1010-02
	Department:	CMO-DOE
	Date:	2016-01-27

1. General Product Description

Foliodrape® Velcro Fastener consists of two pieces and a self-adhesive backing.

Foliodrape® Velcro Fastener 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® Velcro Fastener*, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

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

3. Presentations

Art. No. 938 858	<i>Foliodrape® Velcro Fastener</i>
	sterile, 200 pieces per dispenser, 4 dispenser per transport carton
	Dimensions of dispenser: 300 x 140 x 370 mm (L x W x H)
	Dimensions of transport carton: 590 x 390 x 315 mm (L x W x H)

4. Product Characteristics

Material:	
hook/loop	Nylon/Polyester
adhesive	latex-free, colophonium-free
backing paper	silicone paper
Sterilization:	With ethylene oxide gas according to EN 556-1 and EN 11135-1

5. Product Requirements

hook:	ca. 2 x 21 cm
loop:	ca. 2 x 23 cm

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6. Labelling

Lot-No. with 9-digit code:

e.g.: 6023XXXXX

LOT	6	023	XXXXX
	year of produc- tion	serial production order	for internal use

Expiry date:

e.g. ⌚ 2021 – 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® Velcro fastener is sealed into sterile packaging (peeling pouch) according to EN ISO 11607. The peel pouch is packed into folding box and transport carton, sealed with adhesive tapes and stored on euro-pallet.

Date: 2016-01-27

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