

		<h1>Technical Data Sheet</h1>
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Foliodrape® Sticker, double-sided adhesive	Spec.-No.:	D6.5005
	Department:	CMO-DOE
	Date:	2016-11-16

1. General Product Description

Foliodrape® Sticker, double-sided adhesive, for the fixation of OR drapes (e.g. drape on drape, drape on patient or drape on OR table).

Foliodrape® Sticker, double-sided adhesive, carries the CE-mark according to EU directive 93/42/EWG for medical devices and is classified as class I medical device. 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 of **Foliodrape® Sticker, double-sided adhesive** therefore is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Foliodrape® Sticker, double-sided adhesive is a sterile single use product for the additional fixation of OR drapes (e.g. drape on drape, drape on patient or drape on OR table).

3. Presentations

Art. Nr. 938 999 Foliodrape® Sticker, double-sided adhesive, 6 x 6 cm, sterile, single packed, 100x2 pieces per dispenser, 4 dispenser per transport carton

Dimensions dispenser: 215 x 137 x 156 mm (L x W x H)

Dimensions transport carton: 290 x 230 x 329 mm (L x W x H)

4. Product Characteristics

Material:	
Carrier:	Polyester-film, transparent
Adhesive:	Synthetic rubber, latex- und colophony-free
Protective paper:	Upside: silicone paper white Underside: silicone paper yellow
Sterilisation:	with ethylene oxide gas according to EN 556-1 und EN 11135-1

5. Product Requirements

Dimensions:	ca. 6 x 6 cm
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6. Labelling

e.g.: **6XXX38YYY**

LOT	6	XXX	38	YYY
	year of production	for internal purpose only	week of production	for internal purposes only

Expiry date:

e.g. ⌚ 2021 – 12
year month

Shelf life: 5 years

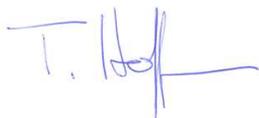
7. Packaging

Foliodrape® Sticker, double-sided adhesive, sealed into peeling Pack (Paper-PA/PE-film), packed into folding box and transport carton acc. DIN EN ISO 11607 and DIN EN 868, sealed with adhesive tapes, packed onto euro-pallet.

Date: 2016-11-16

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i. A.



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