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|  | | <h1>Technical Data Sheet</h1> |
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| Foliodrape® Protect, Basic Set ambu (Art. No. 938 728) |  | Spec.-No.: | D 6.1000m |
| | | Department: | CMO-DOE |
| | | Date: | 2014-06-01 |

1. General Product Description

Foliodrape® Protect Basic Set ambu for smaller abdominal surgeries. Preferred for interventions like hernia, appendectomy, sterilisation etc.

The *Foliodrape® Protect Basic Set ambu* 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® Protect* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of *Foliodrape® Protect Basis Set ambu*, therefore, is ensured if the product is used in line with the intended purpose.

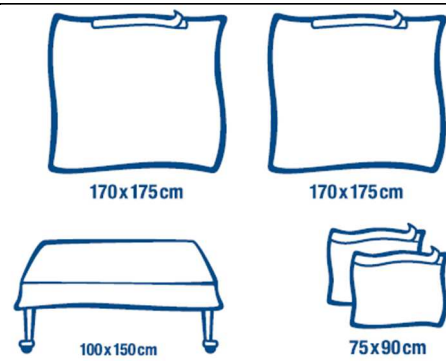
2. Application / Indication


Foliodrape® Protect Basis Set ambu is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations

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|-------------------------|---|
| Art. No. 938 728 | <i>Foliodrape® Protect Basis Set ambu</i> |
| | sterile, 9 Sets per dispenser, 1 dispenser per transport carton |
| | Dimensions of dispenser: 545 x 374 x 234 mm (L x W x H) |
| | Dimensions of transport carton: 590 x 390 x 250 mm (L x W x H) |

4. Product Characteristics

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| Content:  | 1 table cover 150 x 100 cm (2-layer material) |
| | 1 self-adhesive drape sheet 170 x <u>175</u> cm (head) |
| | 1 self-adhesive drape sheet 170 x <u>175</u> cm (foot) |
| | 2 self-adhesive drape sheets 75 x <u>90</u> cm <u>underlined</u> is the side with the adhesive zone on |
| Sterilization: | With ethylene oxide gas according to EN 556-1 and EN 11135-1 |
| Self adhesives: | Skin-friendly synthetic rubber, latex free and colophony free |

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5. Product Requirements

Foliodrape® Protect corresponds to all requirements of European standard for surgical drapes EN 13795, for the highest performance level "High performance, critical area".

For Details see Technical Data sheet of the base material (D 6.1005), and table cover (D 6.1005d).

6. Labelling

Lot-No. with 9-digit code:

e.g.: 5023XXXXX

| | | | |
|-----|--------------------|-------------------------|----------------------------|
| LOT | 5 | XXX | XXXXX |
| | year of production | serial production order | for internal purposes only |

Expiry date:

e.g. ⌚ 2019 – 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® Protect Basis Set ambu 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: 2014-06-01

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i. A.



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