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|  | | Technical Data Sheet | |
| Foliodrape Protect Plus Approach Drapes | |  | Spec.-No.: D 6.1010-01 |
| | | | Department: CMO-DOE |
| | | | Date: 2016-12-07 |

1. General Product Description

Protect Plus Approach drapes made of PE-film, which is impermeable to moisture and bacteria; also available as self-adhesive slit sheet drapes for easy and save application on the patient; for sterile draping of the patient and theatre equipment.

Foliodrape® Protect Plus Approach Drapes carries the CE-mark according to EU directive 93/42/EWG for medical devices. The products are classified as a class I sterile medical devices.

A conformity assessment has been performed for *Foliodrape® Protect Plus Approach Drapes* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of *Foliodrape® Protect Plus Approach Drapes*, therefore, is ensured, if the product is used in line with the intended purpose.

2. Application / Indication

The *Foliodrape® Protect Plus Approach Drape* is a single-use product, which is put on the operating table to make the sterile draping of the patient with the functional drape easier.

3. Presentations



Sterile articles

| | Size (Content per dispenser) | Dispenser per box | Article no. |
|------------------------------------------|--------------------------------------------|-------------------|-------------|
| Approach drapes – simple | 150 x 200 cm (19 pieces) | 2 | 938 831/1 |
| Slit sheet drapes – self-adhesive | 200 x 220 cm, slit 10 x 95 cm, (16 pieces) | 1 | 938 893/1 |
| | 200 x 260 cm, slit 20 x 95 cm, (15 pieces) | 1 | 938 833/1 |

(in blue): the blue number indicates the direction of the slit. Thus, the slit runs parallel to the border which is marked in blue.

4. Product Characteristics

| | |
|----------------------------------|-----------------------------------------------------------------------------------------------------------|
| Film: | Polyethylene-film 60 µm, colour: blue |
| For self-adhesive drapes: | Adhesive based on synthetic rubber, natural rubber latex- and colophony-free; covered with silicone paper |
| Sterilisation | With ethylene oxide gas according EN 556-1 and EN 11135-1 |

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5. Product Requirements (typical values)

The material of *Foliodrape® Protect Plus Approach Drapes* corresponds to all requirements of European standard for surgical drapes EN 13795, for the performance level “High performance, critical product area”.

For details see Technical Data sheet of the base material (D 6.1005g).


6. Labelling

Lot-No. with 9-digit code:

e.g.: 6023XXXXX

| LOT | 6 | 023 | XXXXX |
|-----|--------------------|-------------------------|------------------|
| | year of production | 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® Protect Plus Approach Drapes are wrapped in crepe paper and 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: 2016-12-07

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