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|--|--|----------------------|------------|
|  |  | Technical Data Sheet |            |
| Foliodrape® Protect / Protect Plus,<br>Baby Drape                                |  | Spec.-No.:           | D 6.1002z  |
|  |  | Department:          | CMO-DOE    |
|  |  | Date:                | 2013-01-10 |

#### 1. General Product Description

*Foliodrape® Protect / Protect Plus Baby Drape is made of a soft and high absorbent spunlaced material, consisting of viscose and polyester fibres. The baby drape is a component of the caesarean section sets no. 938 711, 938 720 and 938 904.*

*Foliodrape® Protect / Protect Plus sets carry the CE-mark according to EU directive 93/42/EEG for medical devices and are classified as class I sterile medical devices.*

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

*The safe use of Foliodrape® Protect / Protect Plus sets and their components, therefore, is ensured if the product is used in line with the intended purpose.*

#### 2. Application / Indication

*Foliodrape® Protect / Protect Plus baby drape is a disposable product for covering and wiping a baby directly after his birth.*

#### 3. Presentations


Foliodrape Protect / Protect Plus baby drape is included in the caesarean section sets no. 938 711, 938 720 and 938 904.

#### 4. Product Characteristics

|                              |  |
|------------------------------|--|
| <b>Material composition:</b> | White viscose / polyester spunlaced nonwoven |
| <b>Size:</b>                 | 90 x 100 cm (unfolded)                       |
| <b>Sterilization:</b>        | With ethylene oxide gas                      |

#### 5. Product Requirements (typical values):

|  |                        |
|--|------------------------|
| Grammage:                                | approx. 50 gsm         |
| Tensile Strength (according EN 29073-3): | ≥ 75 N / 50 mm (in MD) |
|  | ≥ 15 N / 50 mm (in CD) |
| Absorbency (according EN ISO 9073-6):    | approx. 800 %          |

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6. Labelling

See relevant set

7. Packaging

*The baby drape is component of the caesarean section sets 938 711, 938 720 and 938 904.  
For details see relevant article.*

8. storage conditions

See relevant article

Date: 2013-01-10

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