
		Technical Data Sheet	
Foliodrape® Protect Plus, base material			Spec.-No.: D 6.1005b
			Department: COM-DOE
			Date: 2018-01-09

### 1. General Product Description

Soft 2-layer material with reinforced zones; consisting of a barrier layer, made of Polyethylene-film (impermeable to moisture and bacteria) and a hydrophilic Polypropylene nonwoven. Pad material consisting of a Polypropylene nonwoven. The material shows a high tensile strength under dry and wet condition and is easy to drape.

Finished products (sets or single products) which are made from the base material carries the CE-mark according to EU directive 93/42/EEG for medical devices.

Patient drapes are classified as class I sterile medical devices.

A conformity assessment has been performed for Foliodrape® Protect Plus 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, therefore, is ensured if the product is used in line with the intended purpose.



### 2. Application / Indication

Single-use product for sterile draping of the patient and the theatre equipment

### 3. Product Characteristics

<b>Composition:</b>	Two-layer nonwoven-Film laminate (55 g/m <sup>2</sup> )+ Absorbent – Pad (55 g/m <sup>2</sup> ), total weight reinforced zone: 110g/m <sup>2</sup> , latex-free
<b>Pad material:</b>	Hydrophilic SMS non woven, colour: green
<b>Nonwoven:</b>	Hydrophilic PP-spunbond, colour: aqua
<b>film:</b>	Pore-free Polyethylene-film, colour: aqua
<b>Laminate bonding:</b>	thermobonding
<b>Adhesive for Pad Fixation:</b>	Hotmelt on base of synthetic rubber
<b>Sterilization:</b>	With ethylene oxide gas


1.		1. Hydrophilic SMS non woven
2.		2. Hydrophilic PP spunbond
3.		3. PE-Film (impermeable for moisture and bacteria)

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#### 4. Product Requirements:

Foliodrape® Protect Plus corresponds to all requirements of European standard EN 13795:2011 + A1:2013 for the highest performance level “High performance, critical area”.

<u>Characteristic</u>	Unit	Requirements according EN 13795 for “High Performance, critical product area”	External laboratory test report result <sup>1)</sup>
<b>Resistance to microbial penetration – dry</b> in accordance with EN ISO 22612	CFU	Not required	Not assessed
<b>Resistance to microbial penetration - wet</b> in accordance with EN ISO 22610	I <sub>B</sub>	6.0	<b>Unreinforced zone:</b> 6.0 (no penetration)  <b>Reinforced zone:</b> 6.0 (no penetration)
<b>Cleanliness – microbial</b> in accordance with EN ISO 11737-1	CFU/ 100cm <sup>2</sup>	≤ 300	Not assessed <sup>2)</sup>
<b>Cleanliness – particulate matter</b> in accordance with EN ISO 9073-10	IPM	≤ 3.5	<b>Unreinforced zone:</b> 1.9  <b>Reinforced zone:</b> 2.5
<b>Linting</b> in accordance with EN ISO 9073-10	Log <sub>10</sub> (lint count)	≤ 4.0	<b>Unreinforced zone:</b> 2.1  <b>Reinforced zone:</b> 2.8
<b>Resistance to liquid penetration</b> in accordance with EN 20811	cm (H <sub>2</sub> O)	≥ 100	<b>Unreinforced zone:</b> > 200 <sup>3)</sup>  <b>Reinforced zone:</b> > 200 <sup>3)</sup>
<b>Bursting strength – dry</b> in accordance with EN ISO 13938-1	kPa	≥ 40	<b>Unreinforced zone:</b> 161 <sup>4)</sup>  <b>Reinforced zone:</b> 361 <sup>4)</sup>
<b>Bursting strength – wet</b> in accordance with EN ISO 13938-1	kPa	≥ 40	<b>Unreinforced zone:</b> 161 <sup>4)</sup>  <b>Reinforced zone:</b> 384 <sup>4)</sup>

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<u>Further Characteristic</u>	Unit	Requirements according EN 13795 for "High Performance, critical product area"	External laboratory test report result <sup>1)</sup>
<b>Tensile strength – dry</b> in accordance with EN 29073-3	[N/50 mm]	≥ 20	<b>Unreinforced zone:</b> cross direction: 46.6 (machine direction: 101)  <b>Reinforced zone:</b> cross direction: 135 (machine direction: 232)
<b>Tensile strength – wet</b> in accordance with EN 29073-3	[N/50 mm]	≥ 20	<b>Unreinforced zone:</b> cross direction: 50.9 (machine direction: 114)  <b>Reinforced zone:</b> cross direction: 144 (machine direction: 248)

- 1) Example Foliodrape® PROTECT PLUS Universal Slit Sheet Set II reinforced 938 739/1 (LOT 699001005), Test report from independent Testing-Institute is available on request
- 2) Foliodrape® articles are sterile according to EN 556
- 3) measured without use of supporting tissue (according to EN 20811)
- 4) values after membrane correction (according to EN ISO 13938-1)

<u>Further characteristics:</u>	Unit	Requirements according EN 13795 for "High Performance critical product area"	Typical Values of Foliodrape® Protect Plus <sup>5)</sup>
<b>Absorbency (lamine)</b> in accordance with EN ISO 9073-6	[%]	No normative requirement	<b>Unreinforced zone:</b> <b>285</b> (△ approx. 156 ml/m <sup>2</sup> )  <b>Reinforced zone:</b> <b>350</b> (△ approx. 386 ml/m <sup>2</sup> )

- 5) Example Foliodrape® PROTECT PLUS Universal Slit Sheet Set II reinforced 938 739/1 (LOT 699001005), Test report from independent Testing-Institute is available on request

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5. Presentations

see relevant article

6. Labelling

see relevant article

7. Packaging

see relevant article

Date: 2018-01-09

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