

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.

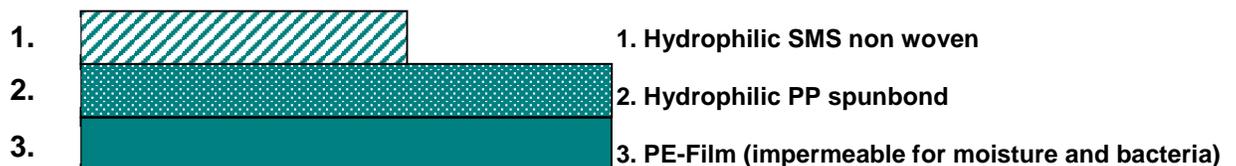
The safe use of Foliodrape® Protect Plus, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

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

3. Product Characteristics

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



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

	<h1>Technical Data Sheet</h1>
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<u>Further Characteristic</u>	<u>Unit</u>	<u>Requirements according EN 13795 for "High Performance, critical product area"</u>	<u>External laboratory test report result¹⁾</u>
Tensile strength – dry in accordance with EN 29073-3	[N/50 mm]	≥ 20	Unreinforced zone: cross direction: 46.6 (machine direction: 101) Reinforced zone: cross direction: 135 (machine direction: 232)
Tensile strength – wet in accordance with EN 29073-3	[N/50 mm]	≥ 20	Unreinforced zone: cross direction: 50.9 (machine direction: 114) Reinforced zone: 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>	<u>Unit</u>	<u>Requirements according EN 13795 for "High Performance critical product area"</u>	<u>Typical Values of Foliodrape® Protect Plus⁵⁾</u>
Absorbency (laminat) in accordance with EN ISO 9073-6	[%]	No normative requirement	Unreinforced zone: 285 (△ approx. 156 ml/m ²) Reinforced zone: 350 (△ approx. 386 ml/m ²)

- 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

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