
		Technical Data Sheet	
Foliodrape® Protect, base material			Spec.-No.: D 6.1005a
			Department: COM-DOE
			Date: 2017-09-06

1. General Product Description

Soft 2-layer material; consisting of a barrier layer, made of Polyethylene-film (impermeable to moisture and bacteria) and a hydrophilic 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 and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Foliodrape® Protect, 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, total weight 55 g/m ² , latex-free
Nonwoven (outside):	Hydrophilic PP-spunbond, 30 g/m ² , colour: aqua
film:	Pore free Polyethylene-film, 25 g/m ² colour: aqua
Laminate bonding:	by thermobonding
Sterilization:	With ethylene oxide gas

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| 1. | | 1. Hydrophilic PP spunbond |
| 2. | | 2. PE-Film (impermeable for moisture and bacteria) |

		<h1>Technical Data Sheet</h1>
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4. Product Requirements:

Foliodrape® Protect corresponds to all requirements of European standard EN13795:2011 +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 ¹⁾
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 (no penetration)	6.0
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	1.9
Linting in accordance with EN ISO 9073-10	Log ₁₀ (lint count)	≤ 4.0	2.1
Resistance to liquid penetration in accordance with EN 20811	cm (H ₂ O)	≥ 100	> 200 ³⁾
Bursting strength – dry in accordance with EN ISO 13938-1	kPa	≥ 40	161 ⁴⁾
Bursting strength – wet in accordance with EN ISO 13938-1	kPa	≥ 40	161 ⁴⁾
Tensile strength – dry in accordance with EN 29073-3	[N/50 mm]	≥ 20	cross direction: 46.6 (machine direction: 101)
Tensile strength – wet in accordance with EN 29073-3	[N/50 mm]	≥ 20	cross direction: 50.9 (machine direction: 114)

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⁾ value after membrane correction (according to EN ISO 13938-1)

		Technical Data Sheet
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<u>Further characteristics:</u>	Unit	Requirements according EN 13795 for "High Performance critical product area"	Typical Values of Foliodrape® Protect ¹⁾
Absorbency (lamine) in accordance with EN ISO 9073-6	[%]	No normative requirement	285 ($\hat{=}$ approx. 156 ml/m ²)

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

5. Presentations

see relevant article

6. Labelling

see relevant article

7. Packaging

see relevant article

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PAUL HARTMANN AG
COM - Development OTM & Exam. Gloves (COM-DOE)



i. A.

Dr. Thomas Hoffmann