		Technical Data Sheet	
Foliodrape® vertical isolation drape film		Spec.-No.:	D 6.1005e
		Deparment:	CMO-DOE
		Date:	2017-06-07

1. General Product Description

Foliodrape® vertical isolation drape film is a transparent Polyethylene film and is used for example for vertical isolation drapes.

Foliodrape® articles which include the vertical drape film carry the CE-mark according to EU directive 93/42/EWG for medical devices and are classified as class I sterile medical devices.

A conformity assessment has been performed for *Foliodrape® vertical isolation drape* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.


The safe use of *Foliodrape® vertical isolation drape film*, 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:	Transparent Polyethylene film (thickness approx. 70 µm, weight approx. 64 g/m ²) latex-free
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4. Product Requirements

Foliodrape® vertical isolation drape film corresponds to all requirements of European standard EN 13795:2011 for the highest performance level "High performance, critical area".

<u>Characteristic</u>	Unit	Requirements according EN 13795 for "High Performance critical product area"	Foliodrape® vertical drape film (typical values)¹⁾
Resistance to microbial penetration – dry in accordance with EN ISO 22612	CFU	Not required	Not required
Resistance to microbial penetration - wet in accordance with EN ISO 22610	I _B	6.0	6.0 (no penetration)
Cleanliness – microbial in accordance with EN ISO 11737-1	CFU/ 100cm ²	≤ 300	sterile according EN 556
Cleanliness – particulate matter in accordance with EN ISO 9073-10	IPM	≤ 3,5	< 1,5
Linting in accordance with EN ISO 9073-10	Log ₁₀ (lint count)	≤ 4,0	< 1,5
Resistance to liquid penetration in accordance with EN 20811	cm (H ₂ O)	≥ 100	> 150 ²⁾
Bursting strength – dry in accordance with EN ISO 13938-1	kPa	≥ 40	>150
Bursting strength – wet in accordance with EN ISO 13938-1	kPa	≥ 40	> 150
Tensile strength – dry in accordance with EN 29073-3	[N/50 mm]	≥ 20	cross direction: > 35 (machine direction: > 50)
Tensile strength – wet in accordance with EN 29073-3	[N/50 mm]	≥ 20	Cross direction: > 35 (machine direction: > 50)

¹⁾ Test report from independent testing-Institute is available on request

²⁾ measured without use of supporting tissue

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5. Presentations

see relevant article

6. Labelling

see relevant article

7. Packaging

see relevant article

Date: 207-06-07

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i. A.



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