HARTMANN		Technical Data Sheet

Foliodrape® Film for Epidural drape (art. no. 938 821) and Angiographie drapes	(Drawing)	Spec.-No.:	D 6.1011f
		Department:	CMO-DOE
		Date:	2017-06-02

1. General Product Description

This *Foliodrape® film* is a transparent Polyethylene film and is used for example for angiographie drapes and one epidural drape.

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 this *Foliodrape® 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. 64 µm, weight approx. 58 g/m^2) latex-free

4. Product Requirements

This Foliodrape® film corresponds to all requirements of European standard EN 13795:2011 for the highest performance level “High performance, critical area”.

Characteristic	**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/ 100cm²	≤ 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_2O)	≥ 100	> 150[2)]
Bursting strength – dry in accordance with EN ISO 13938-1	kPa	≥ 40	> 40
Bursting strength – wet in accordance with EN ISO 13938-1	kPa	≥ 40	> 40
Tensile strength – dry in accordance with EN 29073-3	[N/50 mm]	≥ 20	cross direction: > 35 (machine direction: > 40)
Tensile strength – wet in accordance with EN 29073-3	[N/50 mm]	≥ 20	Cross direction: > 35 (machine direction: > 40)

1) Test report from independent testing-Institute is available on request
2) measured without use of supporting tissue

5. Presentations

   see relevant article

6. Labelling

   see relevant article

7. Packaging

   see relevant article

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