HARTMANN		Technical Data Sheet

Foliodrape® foil split sheet (art. no. 938 818/1)		Spec.-No.:	D 6.5906b
		Department:	CMO-DOE
		Date:	01.06.2014

1. General Product Description

Foliodrape® foil split sheet; impermeable to moisture and bacteria; extra strong, robust film.

Foliodrape® carries the CE-mark according to EU directive 93/42/EWG for medical devices.
The product is classified as a class I medical device.
A conformity assessment has been performed for Foliodrape® and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.
The safe use of Foliodrape®, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Foliodrape® foil split sheet is a disposable product for patient draping.

3. Presentations: steril

Art. Nr. 938 818/1	***Foliodrape*® foil split sheet 150 x 200 cm,** Spil12 x 80 cm
	sterile, 30 pieces per Dispenser, 1 Dispenser per transport carton
	Dimensions of dispenser: 545 x 374 x 234 mm (L x W x H)
	Dimensions of transport carton: 590 x 390 x 250 mm (L x W x H)

4. Product Characteristics:

Composition:	
film:	Polyethylene film, colour: aqua, 60 µm
adhesive:	synthetic rubber based, latex- and colofony-free
Sterilization:	With ethylene oxide gas according EN 556-1 and EN 11135-1

5. Product Requirements (typical values)

Foliodrape® foil split sheet corresponds to all requirements of European standard EN 13795 for the highest performance level “High performance, critical area”.

Characteristic:	**Unit**	**Requirements according EN 13795 for “High Performance, critical product area”**	**Foliodrape® Foil slit sheet (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 in accordance with EN 556
Cleanliness – particulate matter in accordance with EN ISO 9073-10	IPM	≤ 3,5	< 2.5
Linting in accordance with EN ISO 9073-10	Log_{10} (lint count)	≤ 4,0	< 2.5
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	>75[3)]
Bursting strength – wet in accordance with EN ISO 13938-1	kPa	≥ 40	>75[3)]
Tensile strength – dry in accordance with EN 29073-3	[N/50 mm]	≥ 20	cross direction: >30 (machine direction: >40
Tensile strength – wet	[N/50 mm]	≥ 20	cross direction: >30 (machine direction: >40)

1) Test report from independent Testing-Institute is available on request (identical with the film of the table cover)
2) measured without use of supporting tissue
3) values after membrane correction

6. Labelling

Lot-No. with 9-digit code:
e.g.:

LOT	4	XXX	38	YYY
	year	internal code	week of production	internal code

Expiry date:

e.g. ⌛ 2019 12
year month

Shelf life: 5 years
The product will be sterile during this period as long as the packaging is not damaged and the storage conditions are kept.

7. Packaging

Foliodrape® foil split is sealed into sterile packaging (peeling pouch) according to EN ISO 11607 and EN 868. The peel pouch is packed into folding box and transport carton, sealed with adhesive tapes and stored on euro-pallet.

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