



Foliodrape® table cover reinforced



Spec.-No.:	D 6.5410a
Department:	CMO-DOE
Date:	2015-01-13

1. General Product Description

Foliodrape® table cover reinforced; made of film-nonwoven laminate; impermeable to moisture and bacteria; abrasion resistant and low linting, well conformable; absorbent, high puncture resistance, extra strong, robust film.

Foliodrape® carries the CE-mark according to EU directive 93/42/EEG 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® table cover reinforced is a single-use product for sterile draping of the instrument table or additional table and / or for set wrap.

3. Presentations

Foliodrape® table cover reinforced is available as a component in a set or as a single packed product.

Art. Nr. 250 228/4 Foliodrape® table cover reinforced 140 x 160 cm (reinforced area 75x160 cm), steril, 16 pieces per dispenser, 2 dispenser per transport carton
new dispenser format

Art. Nr. 250 226/4 Foliodrape® table cover reinforced 140 x 190 cm (reinforced area 75x190 cm), steril, 14 pieces per dispenser, 2 dispenser per transport carton
new dispenser format

Art. Nr. 938 847/1 Foliodrape® table cover reinforced 150 x 240 cm (reinforced area 75x240 cm), steril, 11 pieces per dispenser, 2 dispenser per transport carton

Art. Nr. 938 848/1 Foliodrape® table cover reinforced 150 x 200 cm (reinforced area 75x200 cm), steril, 14 pieces per dispenser, 2 dispenser per transport carton

Packaging:	Dimensions of dispenser: 275 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)



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4. Product Characteristics: Reinforced table cover

Composition:	non woven-film-laminate, colour: aqua; total weight 90g/m ² , latex-free
film:	PE-film, colour: aqua, 60 µm, width 140 cm or. 150 cm
non-woven :	Polypropylene non-woven, colour: aqua, 30 g/m ² , width 75 cm
adhesive:	Hotmelt on the basis of synthetic rubber, latex-free
Sterilization:	With ethylene oxide gas according EN 556-1 and EN 11135-1

5. Product Requirements: table cover reinforced (typical values)

Foliodrape® table cover reinforced 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® table cover reinforced (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	Film: 6,0 (no penetration) Reinforced zone: 6,0 (no penetration)
Cleanliness – microbial in accordance with EN ISO 11737-1	CFU/ 100cm ²	≤ 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
Characteristic (cont.):	Unit	Requirements according EN 13795 for "High Performance, critical product area"	Foliodrape® table cover reinforced (typical values)*



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Resistance to liquid penetration in accordance with EN 20811	cm (H ₂ O)	≥ 100	Film: >100 ²⁾ Reinforced zone: >150 ²⁾
Bursting strength – dry in accordance with EN ISO 13938-1	kPa	≥ 40	Film: >50 ³⁾ Reinforced zone: >200 ³⁾
Bursting strength – wet in accordance with EN ISO 13938-1	kPa	≥ 40	Film: >50 ³⁾ Reinforced zone: >200 ³⁾
Tensile strength – dry in accordance with EN 29073-3	[N/50 mm]	≥ 20	Film: cross direction: >30 (machine direction: >35) Reinforced zone: cross direction: >60 (machine direction: >90)
Tensile strength – wet in accordance with EN 29073-3	[N/50 mm]	≥ 20	Film: cross direction: >30 (machine direction: >35) Reinforced zone: cross direction: > 60 (machine direction: 90)

- 1) Test report from independent Testing-Institute is available on request
- 2) measured without use of supporting tissue
- 3) values after membrane correction

Further characteristics			
Absorbency (nonwoven) in accordance with EN ISO 9073-6	[%]	---	approx. 450 % ($\hat{=}$ approx. 135 ml/m ²)



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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® table cover reinforced as a component in a set or as a single product, 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.

Date: 2015-01-13

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