
		Technical Data Sheet	
Foliodrape® PROTECT PLUS drapes reinforced		Spec.-No.:	D6.1009a
		Department:	CMO-DOE
		Date:	2016-02-26

1. General Product Description

Foliodrape® PROTECT PLUS drapes made of soft, two-layer material and pad material; impermeable to moisture and bacteria; abrasion-resistant and low linting; well comfortable; self-adhesive drapes with safe adhesive for rapid positioning around the operation site. Extremity drapes and Hand/foot drapes with elastic cuff.

Foliodrape® PROTECT PLUS drapes carry 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® PROTECT PLUS drapes and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use of Foliodrape® PROTECT PLUS, therefore, is ensured if the product is used in line with the intended purpose.



2. Application / Indication

For sterile draping of the patient and theatre equipment.

3. Presentations: sterile

	Size (Content per dispenser)	Dispenser per box	Article no.
Drapes self-adhesive	75 x 75 cm, Pad 36x75 cm, Tape 71 cm (28 Pcs)	4	938 857/1
	75 x 75 cm, Pad 36x75 cm, Tape 71 cm (16x2 Pcs)	4	938 855/1
	75 x 90 cm, Pad 36x90 cm, Tape 86 cm (28 Pcs)	4	938 800/2
	75 x 90 cm, Pad 36x90 cm, Tape 86 cm (16x2 Pcs), in cr.	2	938 856/1
	90 x 100 cm, Pad 35x100 cm, Tape 96 cm (17 Pcs)	4	938 803/2
	150 x 240 cm, Pad 75x50 cm, Tape 90cm (9 Pcs.)	2	938 801/1
	170 x 300 cm, Pad 50x75 cm, Tape 250 cm (7 Pcs.)	2	938 805/1
	200 x 175 cm, Pad 50x75 cm, Tape 90 cm (9 Pcs.)	2	938 802/1
Slit sheet drapes self-adhesive	150 x 240 cm, slit 6.5x65 cm, Pad 60x70 cm (15 Pcs.)	1	938 804/1
	260 x 200 cm, slit 95 cm, Pad 150x160 cm (9 Pcs.)	1	938 806/1
	260 x 200 cm, slit 20x95 cm, Pad 150x160 cm, (7 Pcs.)	1	938 816/1
	280 x 225 cm, slit 10x95 cm, Pad 150x160 cm, (8 Pcs.)	1	938 819/1
Extremity Drapes	320 x 200 cm, fenestr. 5x7 cm, Pad 105x150 cm (10 Pcs.)	1	938 807/1
	320 x 245 cm, fenestr. 5x7 cm, Pad 105x150 cm (8 Pcs.)	1	938 823/1
	320 x 245 cm, fenestr. 3 cm, Pad 105x150 cm (8 Pcs.)	1	938 824/1
Hand-foot-drape	320 x 245 cm, fenestr. 3 cm, Pad 150 x 150 (7 Pcs.)	1	938 808/2

(in blue): the blue number indicates the direction of the adhesive/slit. Thus, the adhesive/slit runs parallel to the border which is marked in blue.

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4. Product Characteristics

Composition:	Two-layer nonwoven-film-laminate + nonwoven-pad
Pad material:	Hydrophilic polypropylene non woven, colour: green
Nonwoven:	Hydrophilic polypropylene nonwoven, colour: aqua
Film:	Polyethylene-film, colour : aqua
Laminate bonding:	Thermobonding
Adhesive for Pad Fixation:	Hotmelt based on synthetic rubber, latex-free
For self-adhesive drapes:	Adhesive based on synthetic rubber, latex- and colophony-free; covered with silicon paper
Sterilisation	With ethylene oxide gas according EN 556-1 and EN 11135-1

5. Product Requirements (typical values)

Foliodrape® PROTECT PLUS drapes corresponds to all requirements of European standard for surgical drapes EN 13795, for the highest performance level "High performance, critical area".

See Technical Data Sheet of the PROTECT PLUS basis material (D6.1005b).

6. Labelling



Lot-No. with 9-digit code:

e.g.: 938 804/1


LOT	4	023	XXXXX
	year	Serial production order	For internal purposes only

e.g.: 938 800/2

LOT	4	XXX	38	YYY
	year of production	for internal purposes only	week of production	for internal purposes only

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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

Drape 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: 2016-02-26

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i. A.



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