
		Technical Data Sheet	
Foliodrape® PROTECT Leggings			Spec.-No.: D 6.5404b
			Department: CMO-DOE
			Date: 02.12.2014

1. General Product Description

Foliodrape® PROTECT Leggings made of soft, two-layer material; bag shaped; impermeable to moisture and bacteria; abrasion-resistant and low linting. highly conformable.

Foliodrape® PROTECT Leggings 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® PROTECT and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Foliodrape® PROTECT Leggings, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Foliodrape® PROTECT Leggings are single-use products for sterile covering of legs when the patient is in the lithotomy position.

3. Presentations

Art. Nr. 938 830 **Foliodrape® PROTECT leggings 75 x 120 cm, paired packed**
sterile, 10x2 pieces per dispenser, 2 dispenser per transport carton

Art. Nr. 938 840 **Foliodrape® PROTECT leggings 75 x 120 cm, single packed**
sterile, 20 pieces per dispenser, 2 dispenser per transport carton


Art. Nr. 938 841 **Foliodrape® PROTECT leggings 75 x 120 cm, paired packed**
sterile, 12x2 pieces per dispenser, 2 dispenser per transport carton

Art. Nr. 938 842 **Foliodrape® PROTECT leggings 75 x 140 cm, single packed**
sterile, 20 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)

4. Product Characteristics

Material:	
basis material:	Two-layer non-woven / film laminate
non-woven : (outer side):	Hydrophilic non-woven, polypropylene, color: aqua
film:	Polyethylene – film, micro-embossed; Color: aqua
seam	Thermal Sealing
Sterilization	With ethylene oxide gas according EN 556-1 and EN 11135-1

Foliodrape® PROTECT Leggings		Spec.-No.:	D 6.5404b
		Department:	CMO-DOE
		Date:	02.12.2014

5. Product Requirements

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

For Details see Technical Data sheet of the base material (D 6.1005f).


6. Labelling

Lot-No. with 9-digit code:

e.g.: **4XXX38YYY**

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

Expiry date:

e.g.  2019 – 01
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® PROTECT Leggings, single or paired packed, 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: 2014-12-02

PAUL HARTMANN AG
CMO- Development OTM & Exam. Gloves (CMO-DOE)

i. A.



Dr. Thomas Hoffmann