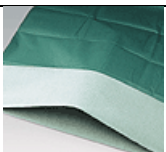
		Technical Data Sheet		
Foliodrape® COMFORT Leggings PE-Film			Spec.-No.:	D 6.5404a
			Department:	CMO-DOE
			Date:	2013-01-23

1. General Product Description

Foliodrape® COMFORT Leggings made of a film; impermeable to bacteria; abrasion-resistant low linting and robust.

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

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

2. Application / Indication

Foliodrape® COMFORT Leggings is a disposable product for sterile covering of legs when the patient is in the lithotomy position.

3. Presentations

Art. No. 258 969

Foliodrape® Comfort leggings 75 x 120 cm, paired packed

Steril, 19 x 2 pieces per dispenser, 2 dispenser per transport carton

4. Product Characteristics

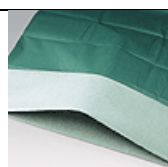
Material:	
Basis material:	PE-film
Sterilization	by radiation

5. Product Requirements

Foliodrape® Comfort 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 from the back table cover just the PE Film (D 6.5410a).

		Technical Data Sheet
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Foliodrape® COMFORT Leggings PE-Film		Spec.-No.:	D 6.5404a
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6. Labelling

Lot-No. with 9-digit code:

e.g.: 9XXX38YYY

LOT	9	XXX	38	YYY
	year	for internal purpose only	week of production	for internal purpose only

Expiry date:

e.g.:  2014 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® COMFORT Leggings 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: 2013-01-23

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

i. A.



Dr. Thomas Hoffmann