



Technical Data Sheet

**Foliodrape® Protect,
Ophthalmology Set III
(Art. No. 938 936)**



Spec.-No.:	D 6.1012f
Department:	CMO-DOE
Date:	2014-11-13

1. General Product Description

Foliodrape® Protect Ophthalmology Set III for all kind of eye surgery.

The *Foliodrape® Protect Ophthalmology Set III* carries the CE-mark according to EU directive 93/42/EWG for medical devices and is classified as class I sterile medical devices. 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 Ophthalmology Set III*, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Foliodrape® Protect Ophthalmology Set III is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations

Art. No. 938 936	<i>Foliodrape® Protect Ophthalmology Set III</i>
	sterile, 10 Sets per dispenser, 2 dispenser per transport carton
	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

Content:	1 back table cover reinforced 140 x 160 cm
	1 ophthalmology drape 150 x 150 cm with fenestration (6,5 x 4 cm), self adhesive and fluid collection bag
Sterilization:	With ethylene oxide gas according to EN 556-1 and EN 11135-1
Self adhesives:	Skin-friendly synthetic rubber, latex free and colophony free



Technical Data Sheet

**Foliodrape® Protect,
Ophthalmology Set III
(Art. No. 938 936)**



Spec.-No.:	D 6.1012f
Department:	CMO-DOE
Date:	2014-11-13

5. Product Requirements

Foliodrape® Protect Ophthalmology Set III 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 6.1005a) and back table cover (D 6.1005d).

6. Labelling

Lot-No. with 9-digit code:

e.g.: 1023XXXXX

LOT	1	023	XXXXX
	year of production	serial production order	for internal use

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 Ophthalmology Set III 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: 2014-11-13

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

i. A.

Dr. Evelyn Hartmann