

# RAUCODRAPE® fenestrated drape, sterile

REF 33041, 33043

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Translation: PAGRA

## 1. Composition of the product

The RAUCODRAPE® fenestrated drape is composed of the following:

- 2-layered RAUCODRAPE® material consisting of
  - nonwoven fabric: 100% polypropylene fibres, hydrophilic, blue-green
  - film: 100% polyethylene, blue-green

The individual layers are continuously laminated with hotmelt glue.

- adhesive strips consisting of
  - self-adhesive, thermoplastic hotmelt glue (synthetic rubber)
  - 100% polyester film base, transparent
  - siliconized pergamin paper, white

This Product Data Sheet applies to the following items:

REF 33041	RAUCODRAPE® fenestrated drape	50 x 60 cm	2-layered, sterile
REF 33043	RAUCODRAPE® fenestrated drape	75 x 90 cm	2-layered, sterile

## 2. Packaging, structure and composition

### 2.1 Unit container

- Four-edge sealed pouch consisting of cellulose, polyamide, and polyethylene

### 2.2 Shelf container

- Cellulose folding box

### 2.3 Transit container

- Corrugated cardboard carton (cellulose)

### 3. **Manufacture**

The RAUCODRAPE® fenestrated drape is produced according to specification in hygienic conditions, and packed in accordance with applicable packaging specifications.

The product is sterilized by use of ethylene oxide in compliance with DIN EN ISO 11135-1.

### 4. **Description**

2-layered fenestrated drape, available in 2 different sizes. The RAUCODRAPE® fenestrated drape is folded ready for use and individually packed in sterile packaging.

### 5. **Properties**

The structure/composition of RAUCODRAPE® materials prevents penetration of liquids and bacteria on the entire covering surface, with the polyethylene film acting as a barrier against microorganisms.

The RAUCODRAPE® fenestrated drape is **latex-free**, absorbent, and tear-resistant, with a low particle content and good draping behaviour.

RAUCODRAPE® products made from the above materials are intended for single use only and must not be resterilized.

### 6. **Intended purpose**

The RAUCODRAPE® fenestrated drape is intended for covering patients during surgery.

### 7. **Medical device classification**

The RAUCODRAPE® fenestrated drape is a medical device of Class Is according to Rule 1, Annex IX of the Council Directive 93/42/EEC concerning medical devices.

### 8. **Biological evaluation and biocompatibility (DIN EN ISO 10993)**

According to the clinical assessment and risk analysis performed, the RAUCODRAPE® fenestrated drape is pharmacologically-toxicologically harmless if used appropriately and for the purposes intended.

The material used meets the requirements of EN 13795-3:2006.

To date this company has received no notification of incidents involving this Lohmann & Rauscher product; neither has there been any need for a recall based on poor quality.

The purpose of this documentation and of the statements made therein is to show that the medical device RAUCODRAPE® fenestrated drape is designed, manufactured, and packaged in such a way that its use presents no hazard or risk to the patients' clinical condition or safety, nor to the safety and health of the user or other persons when used under the conditions and for the purposes intended.

## **9. Stability**

Stored appropriately, the RAUCODRAPE® fenestrated drape has a shelf life of 5 years.

## **10. Disposal**

The user is advised to observe current national legislation, standards, and guidelines regulating the disposal of medical refuse.

Packaging materials must also be disposed of in compliance with applicable national requirements.

Lohmann & Rauscher International GmbH & Co. KG  
D-56579 Rengsdorf  
signed by  
Dr. Martin Abel  
(Medical & Regulatory Affairs)