

# **RAUCODRAPE<sup>®</sup> drape sheet, sterile**

**REF: 33001, 33002, 33003**

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## **1. Composition of the product**

The material consists of a 2-layered hydrophilic nonwoven polypropylene fabric and a polyethylene film.

- nonwoven fabric: 100% polypropylene fibres, hydrophilic, white
- film: 100% polyethylene, blue-green

The individual layers are continuously laminated with hotmelt glue.

This Product Data Sheet applies to the following items:

REF 33001	Raucodrape <sup>®</sup> drape sheet,	38 x 45 cm,	2-layered, sterile
REF 33002	Raucodrape <sup>®</sup> drape sheet,	45 x 75 cm,	2-layered, sterile
REF 33003	Raucodrape <sup>®</sup> drape sheet,	75 x 90 cm,	2-layered, sterile

## **2. Packaging, structure and composition**

### **2.1 Unit container**

Peel 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® drape sheet 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**

The RAUCODRAPE® drape sheet is folded ready for use and individually wrapped in sterile packaging. The product is available in three different sizes.

### 5. **Properties**

The structure/composition of materials in the RAUCODRAPE® O.R. drape systems prevents penetration of liquids and bacteria on the entire covering surface, with the polyethylene film acting as a 100% safe barrier against microorganisms. The RAUCODRAPE® adhesive drape is **latex-free**, absorbent, and tear-resistant, with a low particle content and good draping behaviour. The RAUCODRAPE® drape sheet is intended for one-time use only; it must not be resterilized.

### 6. **Intended purpose**

The RAUCODRAPE® drape sheet is intended for covering patients, O.R. furniture, and equipment during surgery.

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

As the RAUCODRAPE® drape sheet is used for covering patients as well as O.R. furniture and equipment, it 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® drape sheet is medico-pharmacologically harmless if used appropriately and for the purposes intended.

The RAUCODRAPE® 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 need for a recall for reasons of quality.

The purpose of this documentation and of the statements made therein is to show that there is no risk involved in the use of the medical device RAUCODRAPE® drape sheet and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

## **9. Stability**

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

## **10. Disposal**

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

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

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signed by  
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(Medical & Regulatory Affairs)