

RAUCODRAPE® adhesive drape, sterile

REF 33010 – 33013, 33016, 33018, 33020, 33022, 33025

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Translation: PAGRA

1. Composition of the product

The RAUCODRAPE® adhesive drape is composed of the following:

- 2-layered RAUCODRAPE® material consisting of
 - nonwoven fabric: 100% polypropylene fibres, hydrophilic, blue-green
 - film: 100% polyethylene, blue-greenThe 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 33010	RAUCODRAPE® adhesive drape	50 x 50 cm,	2-layered, sterile
REF 33011	RAUCODRAPE® adhesive drape	50 x 75 cm,	2-layered, sterile
REF 33012	RAUCODRAPE® adhesive drape	75 x 75 cm,	2-layered, sterile
REF 33013	RAUCODRAPE® adhesive drape	75 x 90 cm,	2-layered, sterile
REF 33016	RAUCODRAPE® adhesive drape	175 x 180 cm,	2-layered, sterile
REF 33018	RAUCODRAPE® adhesive drape	150 x 240 cm,	2-layered, sterile
REF 33020	RAUCODRAPE® adhesive drape	90 x 110 cm,	2-layered, sterile
REF 33022	RAUCODRAPE® instrument collection drape	90 x 150 cm,	2-layered, sterile
REF 33025	RAUCODRAPE® adhesive drape	150 x 180 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® adhesive drape is produced according to specification in hygienic conditions, and wrapped 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 adhesive drape with adhesive strips, available in different sizes. The RAUCODRAPE® adhesive drape is folded ready for use and individually wrapped 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® adhesive 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® adhesive drape is intended for covering patients during surgery.

7. Medical device classification

The RAUCODRAPE® adhesive 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® adhesive 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® adhesive 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 any other persons when used under the conditions and for the purposes intended.

9. Stability

Stored appropriately, the RAUCODRAPE® adhesive 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.

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signed by
Dr. Martin Abel
(Medical & Regulatory Affairs)