RAUCODRAPE®
OR-Drape Sheet, sterile

REF 33004, 33008, 33009, 33190

May 2015

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1. Composition of the product

The RAUCODRAPE® OR-Drape Sheet consists of two layers and has the following material composition:

- nonwoven: polypropylene, hydrophilic, blue-green
- film: polyethylene, blue-green

The individual layers are glued together with a hotmelt adhesive.

This product data sheet covers the following items:

REF 33004, Raucodrape® OR-Drape Sheet, 150 x 240 cm, 2-layers, sterile
REF 33008, Raucodrape® OR-Drape Sheet, 100 x 150 cm, 2-layers, sterile
REF 33009, Raucodrape® OR-Drape Sheet, 150 x 180 cm, 2-layers, sterile
REF 33190, Raucodrape® OR-Drape Sheet, 90 x 110 cm, 2-layers, sterile

2. Packaging, structure and composition

2.1 Unit container

- peel pouch consisting of cellulose, polyamide, and polyethylene

2.2 Shelf container

- folding box made of cellulose

2.3 Transit container

- corrugated cardboard box made of cellulose

3. Manufacture

The RAUCODRAPE® OR-Drape Sheet is manufactured in hygienic conditions according to specification, functionally folded, individually packed and sterile.
The product is sterilized by ethylene oxide in accordance with DIN EN ISO 11135-1.

4. Description

2-layered surgical drape which is available in 3 different sizes. The RAUCODRAPE® OR-Drape Sheet is functionally folded and individually packed in sterile packaging.

5. Properties

The RAUCODRAPE® OR-Drape Sheet is a highly absorbent, liquid-tight and bacteria-proof drape.
The RAUCODRAPE® OR-Drape Sheet is tear-resistant, low in particles and **free of natural latex** with a good draping behaviour.
The RAUCODRAPE® OR-Drape Sheet is sterile as long as the package remains unopened and undamaged.

6. Intended purpose

The RAUCODRAPE® OR-Drape Sheet is intended for draping patients or equipment during surgical interventions.

7. Medical device classification

The RAUCODRAPE® OR-Drape Sheet is a medical device of Class Is according to Rule 1.
(Annex IX of the Council Directive 93/42/EEC covering medical devices)

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

Based on the clinical evaluation and risk analysis carried out the medical-pharmacological safety of RAUCODRAPE® OR-Drape Sheet is guaranteed providing it is used appropriately and for the purposes intended.

The material used fulfils the requirements of EN 13795.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device RAUCODRAPE® OR-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 RAUCODRAPE® OR-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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