

ROSIDAL[®] soft Foam bandage

REF 13016, 23100 - 23103, 23110 - 23113

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1. Composition of the product

The ROSIDAL[®] soft foam bandage consists of

- polyester-based polyurethane foam
- bandage clips of two aluminium hooks connected via rubber cord

The ends of the bandage are held in place by transfer labels consisting of waxed paper and an adhesive layer of polyurethane and polyamide.

This Product Data Sheet applies to the following items:

REF 13016	Rosidal [®] soft	10 cm x 2.0 m x 0.2 cm
REF 23100	Rosidal [®] soft	10 cm x 2.5 m x 0.3 cm
REF 23101	Rosidal [®] soft	10 cm x 2.5 m x 0.4 cm
REF 23102	Rosidal [®] soft	12 cm x 2.5 m x 0.4 cm
REF 23103	Rosidal [®] soft	15 cm x 2.5 m x 0.4 cm
REF 23110	Rosidal [®] soft	10 cm x 2.5 m x 0.3 cm
REF 23111	Rosidal [®] soft	10 cm x 2.5 m x 0.4 cm
REF 23112	Rosidal [®] soft	12 cm x 2.5 m x 0.4 cm
REF 23113	Rosidal [®] soft	15 cm x 2.5 m x 0.4 cm

2. Packaging, structure and composition

2.1. Unit container

- REF 23110 - 23113, 13016 s. 2.2
- REF 23100 - 23103 s. 2.3

2.2 Shelf container

- REF 23110 - 23113, 13016
- cellulose folding box

2.3. Transit container

- corrugated cardboard box (cellulose)

3. Manufacture

The ROSIDAL® soft foam bandage is made of polyurethane foam and packaged according to its specification.

4. Description

The ROSIDAL® soft foam bandage is white, fine porous, light and elastic.

5. Properties

ROSIDAL® soft foam bandages are permeable to water vapour. The material is extremely stable and possesses high tensile strength and very good resistances to abrasion and tear propagation.

The bandage is ideal for padding limbs underneath compression bandaging in lymphology and phlebology. The padding distributes evenly the compression exerted on a limb by a ROSIDAL® K short stretch bandage, thus making the therapy safe by avoiding constriction.

Slippage is prevented as the open pores of the non-irritant ROSIDAL® soft foam bandage take hold of each other.

The bandage can be washed up to 95°C (temperatures from 40 to 60°C are recommended).

Non-sterile ROSIDAL® soft foam bandages can be sterilized by steam or ethylene oxide according to DIN EN ISO 17665-1 or DIN EN ISO 11135-1 respectively.

6. Intended purpose

Elastic foam bandage for padding limbs underneath compression bandaging in lymphology and phlebology. They are also suitable as underwrap bandages under orthopedic casts as well as for padding wanted over wound dressings, cannula or splints.

7. Medical device classification

Used for padding limbs underneath compression bandaging in lymphology and phlebology, ROSIDAL® soft foam bandages are medical devices of Class I in terms of Rule 1 (Council Directive 93/42/EEC concerning medical devices, Annex IX).

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

For padding extremities. The ROSIDAL® soft foam bandage has direct contact with healthy and unscarified skin only.

The starting materials used in the manufacture of the ROSIDAL® soft foam bandage are safe when the product is used for its intended purposes.

To date our company has received no notification of any 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 “ROSIDAL® soft foam bandage” is designed, manufactured, and packaged in such a manner 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 third parties involved, provided that the product is used under the conditions and for the purposes intended.

9. Stability

Stored appropriately, the ROSIDAL® soft foam bandage 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.

Lohmann & Rauscher International GmbH & Co. KG
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signed by
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(Medical & Regulatory Affairs)