

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

- polyurethane foam based on polyester
- bandage clips consisting of two aluminium hooks connected by a latex-free rubber heddle.

This Product Data Sheet applies to the following items:

REF	Product name	Width x Length x Thickness	Packaging
13016	Rosidal [®] soft	10 cm x 2,0 m x 0,2 cm	2 pcs. In folding box
23100	Rosidal [®] soft	10 cm x 2,5 m x 0,3 cm	bulk in a cardboard box
23101	Rosidal [®] soft	10 cm x 2,5 m x 0,4 cm	bulk in a cardboard box
23102	Rosidal [®] soft	12 cm x 2,5 m x 0,4 cm	bulk in a cardboard box
23103	Rosidal [®] soft	15 cm x 2,5 m x 0,4 cm	bulk in a cardboard box
23110	Rosidal [®] soft	10 cm x 2,5 m x 0,3 cm	Individually packed in folding box
23111	Rosidal [®] soft	10 cm x 2,5 m x 0,4 cm	Individually packed in folding box
23112	Rosidal [®] soft	12 cm x 2,5 m x 0,4 cm	Individually packed in folding box
23113	Rosidal [®] soft	15 cm x 2,5 m x 0,4 cm	Individually packed in folding box

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 produced according to specification in hygienic conditions and packed as described in the relevant packaging specification.

4. Description

The ROSIDAL® soft is a white and fine porous foam bandage.

5. Properties

The ROSIDAL® soft is a lengthwise and widthwise stretchable foam bandage. The material is tear-resistant and permeable to air and moisture. The bandages can be washed up to 50 times at max. 95 °C; the product maintains its elasticity and cushioning effect even after washing.

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.

Natural rubber latex is not an intentional ingredient in the production of the above mentioned products or its packaging. However, to the best of our knowledge we can't completely exclude any potential contaminations with latex traces from the production or the environment.

6. Intended purpose

ROSIDAL® soft Foam Bandages are intended to be used as a padding material under compression bandages in lymphology and phlebology.

7. Medical device classification

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)

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

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. The surface of the product can turn yellow during storage.

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
Dr. Martin Abel
(Medical & Regulatory Affairs)