

KOMPREX® II

REF 16985

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1. Composition of the product

KOMPREX® II Foam Sheet, wavy, consists of:

- a polyester pile fabric
- a polyurethane foam
- a knitted polyester fabric

This product data sheet applies to the following items:

REF 36301 Komprex® II Wavy Foam Sheet 26 in x 26 in

2. Packaging, structure and composition

2.1. Unit Container

- see 2.2.

2.2. Shelf Container

- paper wrapping (cellulose)
- polyethylene flat bag

2.3. Transit Container

- corrugated cardboard box (cellulose)

3. Manufacture

KOMPREX® II is produced according to specification in hygienic conditions and packed in accordance with applicable packaging specifications.

4. Description

Wavy, white foam sheet whose ribs are individually sealed by ultrasonic grid welding. The sheet measures 26 in x 26 in and the ribs are about 1 cm wide.

5. Properties

Narrow foam ribs covered in skin-friendly nonwoven result in padding which allows the air to pass through and which does not slip.

Because of its unusual surface structure KOMPRES® II has a distinct and gentle massaging effect.

6. Intended purpose / use

The KOMPRES® II is intended for padding in compression bandaging.

7. Medical device classification

The KOMPRES® II is medical devices of Class I according to Rule 1. (Council Directive 93/42/EEG concerning medical devices, Annex IX)

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

The starting materials used in the manufacture of KOMPRES® II are safe if the product is used appropriately and for the purposes intended purposes.

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 KOMPRES® II 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 KOMPRES® II has a shelf life of 5 years.

10. Disposal

The user is advised to observe current national 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)