

MOLLELAST®

Conforming Bandage

REF 19410 – 19414
 REF 19427 – 19429
 REF 34514 – 34517

REF 34511 – 34513
 REF 14410 – 14414

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 Modification: MI / S. Golz

1. Composition of the product

This Mollelast® bandage consists of:

- viscose
- polyamide

This product data sheet covers the following items:

| | | |
|-----------|---------------|---|
| REF 19410 | Mollelast® | 4 cm x 4 m stretched, 20 pcs. packed in a folding box |
| REF 19411 | Mollelast® | 6 cm x 4 m stretched, 20 pcs. packed in a folding box |
| REF 19412 | Mollelast® | 8 cm x 4 m stretched, 20 pcs. packed in a folding box |
| REF 19413 | Mollelast® | 10 cm x 4 m stretched, 20 pcs. packed in a folding box |
| REF 19414 | Mollelast® | 12 cm x 4 m stretched, 20 pcs. packed in a folding box |
| REF 34511 | Mollelast®V2D | 6 cm x 4 m stretched, 20 pcs. packed in a folding box |
| REF 34512 | Mollelast®V2D | 8 cm x 4 m stretched, 20 pcs. packed in a folding box |
| REF 34513 | Mollelast®V2D | 10 cm x 4 m stretched, 20 pcs. packed in a folding box |
| REF 19427 | Mollelast® | 6 cm x 4 m stretched, 100 pcs. packed in a folding box |
| REF 19428 | Mollelast® | 8 cm x 4 m stretched, 100 pcs. packed in a folding box |
| REF 19429 | Mollelast® | 10 cm x 4 m stretched, 100 pcs. packed in a folding box |
| REF 14410 | Mollelast® | 4 cm x 4 m stretched, individually sealed |
| REF 14411 | Mollelast® | 6 cm x 4 m stretched, individually sealed |
| REF 14412 | Mollelast® | 8 cm x 4 m stretched, individually sealed |
| REF 14413 | Mollelast® | 10 cm x 4 m stretched, individually sealed |
| REF 14414 | Mollelast® | 12 cm x 4 m stretched, individually sealed |
| REF 34514 | Mollelast®V2D | 4 cm x 4 m stretched, individually sealed |
| REF 34515 | Mollelast®V2D | 6 cm x 4 m stretched, individually sealed |
| REF 34516 | Mollelast®V2D | 8 cm x 4 m stretched, individually sealed |
| REF 34517 | Mollelast®V2D | 10 cm x 4 m stretched, individually sealed |

2. Packaging, structure and composition

2.1 Unit container

- REF 19410 - 19414 and REF 19427 – 19429
- REF 34511 – 34513 see 2.2

- REF 14410 - 14414 and REF 34514 - 34517 full wrap of polypropylene film

2.2 Shelf container

- a folding cardboard box (cellulose)

2.3 Transit container

- corrugated cardboard box (cellulose)

3. Manufacture

The Mollelast® bandage is produced according to specification and under hygienic conditions. It is packed as described in its respective packaging specification.

4. Description

These are elastic bandages with firm edges produced in a warp knitting technique. The white to cream-coloured elastic bandages are wound onto themselves. They are available in various widths, all having a stretched length of 4 m.

5. Properties

Mollelast® bandages are conforming bandages which are elastic in the length by approx. 100 %. They are permeable to air and thus non-irritant / skin-friendly. Mollelast® bandages are non-sterile and can be sterilized by steam in compliance with DIN EN ISO 17665-1 if necessary.

Natural rubber latex is not an intentional ingredient in the production of the above mentioned products. 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 (see valid instructions for use)

Mollelast® bandages are intended for the immobilization of body parts, for the retention of dressings and/or for compression purposes.

7. Medical device classification

The Mollelast® bandage is a medical device 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 Mollelast® bandages are safe provided the product is used appropriately and for the purposes intended.

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 Mollelast® bandage 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, Mollelast® bandages have 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
Dr. Martin Abel
(Medical & Regulatory Affairs)