

MOLLELAST®

Elastic Conforming Bandage

REF 19410 – 19414 REF 34511 – 34517 REF 19427 – 19429 REF 14410 – 14414 REF 2014820 – 2014821 REF 2015457-2015459

February 2021

1. Composition of the product

This Mollelast® bandage consists of:

- viscose
- polyamide

This product data sheet covers the following items:

| REF | Product description | Feature |
|---------|------------------------|-----------------------|
| 19410 | Mollelast [®] | 4 cm x 4 m stretched |
| 19411 | Mollelast [®] | 6 cm x 4 m stretched |
| 19412 | Mollelast [®] | 8 cm x 4 m stretched |
| 19413 | Mollelast [®] | 10 cm x 4 m stretched |
| 19414 | Mollelast [®] | 12 cm x 4 m stretched |
| 34511 | Mollelast® SG2 | 6 cm x 4 m stretched |
| 34512 | Mollelast® SG2 | 8 cm x 4 m stretched |
| 34513 | Mollelast® SG2 | 10 cm x 4 m stretched |
| 34514 | Mollelast® SG2 | 4 cm x 4 m stretched |
| 34515 | Mollelast® SG2 | 6 cm x 4 m stretched |
| 34516 | Mollelast® SG2 | 8 cm x 4 m stretched |
| 34517 | Mollelast® SG2 | 10 cm x 4 m stretched |
| 19427 | Mollelast [®] | 6 cm x 4 m stretched |
| 19428 | Mollelast [®] | 8 cm x 4 m stretched |
| 19429 | Mollelast [®] | 10 cm x 4 m stretched |
| 14410 | Mollelast [®] | 4 cm x 4 m stretched |
| 14411 | Mollelast [®] | 6 cm x 4 m stretched |
| 14412 | Mollelast [®] | 8 cm x 4 m stretched |
| 14413 | Mollelast [®] | 10 cm x 4 m stretched |
| 14414 | Mollelast [®] | 12 cm x 4 m stretched |
| 2014820 | Mollelast | 12 cm x 4 m |
| 2014821 | Mollelast | 8 cm x 4 m |
| 2015457 | Mollelast | 10 cm x 4 m |
| 2015458 | Mollelast | 6 cm x 4 m |
| 2015459 | Mollelast | 4 cm x 4 m |

2. Packaging, structure and composition

2.1 Unit container

- see 2.2.

2.2 Shelf container

- folding box consisting of cellulose

| REF | pieces per folding box | |
|------------------------------|------------------------------------|--|
| 19410 – 19414; 34511 - 34513 | 20 | |
| 19427 - 19429 | 100 | |
| 14410 - 14414; 34514 – 34517 | individually packed, 20 pieces per | |
| | folding box | |

2014820, 2014821, 2015457, 2015458, 2015459: see 2.3

2.3 Transit container

- corrugated cardboard box made of cellulose

| REF | pieces per corrugated cardboard box | folding boxes |
|----------------------------|-------------------------------------|---------------|
| 14410; 19410; 34514 | 520 | 26 |
| 14411; 14413; 19411; | 360 | 18 |
| 19413; 34511; 34513; | | |
| 34515; 34517 | | |
| 14412; 19412; 34512; 34516 | 500 | 25 |
| 14414; 19414 | 320 | 16 |
| 19427; 19428 | 400 | 4 |
| 19429 | 300 | 3 |
| 2014820 | 500 | - |
| 2014821 | 750 | - |
| 2015457 | 550 | - |
| 2015458 | 990 | - |
| 2015459 | 1.500 | - |

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

The Mollelast® bandage is a longitudinal elastic fixation bandage. The product is non-sterile.

5. Properties

- o lengthwise elastic (to about 100%)
- o air-permeable and textured
- o does virtually not crease when applied
- o retains reliably even on tapered parts of the body and joints
- white, with selvedges

6. Intended purpose

Fixation Bandages are intended to be used for retention, for immobilization and for lymphological compression of fingers and toes.

7. Medical device classification

The Mollelast[®] bandage is a medical device of Class I in terms of Rule 1 (according to directive 93/42/EEC and regulation (EU) 2017/745).

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. Requirements regarding the safety/harmlessness of the constituents

Currently we have no information on questionable ingredients.

10. Stability

Stored appropriately (keep dry, protected from dust and light) Mollelast[®] bandages have a shelf life of 5 years from the date of manufacture.

11. 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 D-56579 Rengsdorf signed by Peter Grillitsch Head of Global Marketing