

Mollelast® haft

Cohasive Conforming Bandage, free of natural rubber latex

REF 89590 – 89602

April 2019

1. Composition of the product

This Mollelast® haft bandage, free of natural rubber latex, consists of:

- viscose
- polyamide
- a coating free of natural rubber latex (on both sides)

This product data sheet covers the following items:

REF	Product description	Size
89590	Mollelast® haft, free of natural rubber latex	4 cm x 4 m stretched
89591	Mollelast® haft, free of natural rubber latex	6 cm x 4 m stretched
89592	Mollelast® haft, free of natural rubber latex	8 cm x 4 m stretched
89593	Mollelast® haft, free of natural rubber latex	10 cm x 4 m stretched
89594	Mollelast® haft, free of natural rubber latex	12 cm x 4 m stretched
89595	Mollelast® haft, free of natural rubber latex	4 cm x 20 m stretched
89596	Mollelast® haft, free of natural rubber latex	6 cm x 20 m stretched
89597	Mollelast® haft, free of natural rubber latex	8 cm x 20 m stretched
89598	Mollelast® haft, free of natural rubber latex	10 cm x 20 m stretched
89599	Mollelast® haft, free of natural rubber latex	12 cm x 20 m stretched
89600	Mollelast® haft, free of natural rubber latex	6 cm x 20 m stretched
89601	Mollelast® haft, free of natural rubber latex	8 cm x 20 m stretched
89602	Mollelast® haft, free of natural rubber latex	10 cm x 20 m stretched

2. Packaging, structure and composition

2.1 Unit container

see 2.2

2.2 Shelf container

1 folding cardboard box (cellulose)

REF	pcs.
89590 - 89599	1
89600 - 89602	6

2.3 Transit container

1 corrugated cardboard box (cellulose)

REF	folding boxes
89590, 89592, 89593	120
89591, 89594	100
89596 - 89599	18
89600 - 89602	4

3. Manufacture

Mollelast® haft bandages, free of natural rubber latex, are produced according to specification in hygienic conditions. They are wound on cardboard cores and - as described in their respective packaging specification - packed individually in [respectively 6 pcs. packed into]

If required, the product can be sterilized by moist heat or ethylene oxide in conformity with DIN EN ISO 17665 part 1-3 or DIN EN ISO 11135 respectively.

Steam sterilization will increase the products resistance to unwinding and reduce its extensibility.

4. Description

These are elastic bandages with firm edges produced in a “knitting cum weaving technique”. The cohesive finish allows bandage tours to cling to each other, making bandage clips for securing bandage ends obsolete.

Mollelast® haft bandages, free of natural rubber latex, are available in various sizes.

5. Properties

Mollelast® haft bandages, free of natural rubber latex, are conforming bandages which are elastic in the length by approx. 65 % and extensible in the width. They are cohesive, allow the skin to breathe and are non-irritant / skin-friendly. The coating (on both sides) is free of natural rubber latex.

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 (see valid instructions for use)

Mollelast® haft bandages, free of natural rubber latex, are intended for the immobilization of body parts, for the retention of dressings and cannulas, and/or for compression purposes.

7. Medical device classification

Mollelast® haft bandages, free of natural rubber latex, 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 Mollelast® haft bandages, free of natural rubber latex, 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® haft bandage, free of natural rubber latex, 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 – at room temperature and air humidity of not more than 60 % - Mollelast® haft bandages, free of natural rubber latex, have a shelf life of 3 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.

Lohmann & Rauscher International GmbH & Co. KG

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signed by

Dr. Klemens Schulz

Executive Board/ Chief Portfolio Officer