

PRODUCT DATA SHEET E-0633

# **MOLLELAST<sup>®</sup> HAFT Conforming Bandage**

REF 30063 – 30072; 109510; 82691; 82693; 82697; 82700 REF 2001591; 2001593 – 2001594; 2001597

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## 1. Composition of the product

This Mollelast® haft consists of:

- viscose
- polyamide
- coated with natural latex

This product data sheet covers the following items:

REF	Product description	Feature
30063	MOLLELAST <sup>®</sup> haft Conforming Bandage	4 cm x 4 m, stretched
30064	MOLLELAST <sup>®</sup> haft Conforming Bandage	6 cm x 4 m, stretched
30065	MOLLELAST <sup>®</sup> haft Conforming Bandage	8 cm x 4 m, stretched
30066	MOLLELAST <sup>®</sup> haft Conforming Bandage	10 cm x 4 m, stretched
30067	MOLLELAST <sup>®</sup> haft Conforming Bandage	12 cm x 4 m, stretched
30068	MOLLELAST <sup>®</sup> haft Conforming Bandage	4 cm x 20 m, stretched
30069	MOLLELAST <sup>®</sup> haft Conforming Bandage	6 cm x 20 m, stretched
30070	MOLLELAST <sup>®</sup> haft Conforming Bandage	8 cm x 20 m, stretched
30071	MOLLELAST <sup>®</sup> haft Conforming Bandage	10 cm x 20 m, stretched
30072	MOLLELAST <sup>®</sup> haft Conforming Bandage	12 cm x 20 m, stretched
109510	MOLLELAST <sup>®</sup> haft blanche	4 cm x 4 m, stretched
82691	MOLLELAST <sup>®</sup> haft blanche	6 cm x 4 m, stretched
82693	MOLLELAST <sup>®</sup> haft blanche	8 cm x 4 m, stretched
82697	MOLLELAST <sup>®</sup> haft blanche	10 cm x 4 m, stretched
82700	MOLLELAST <sup>®</sup> haft blanche	12 cm x 4 m, stretched
2001591	MOLLELAST <sup>®</sup> haft loose in big box	4 cm x 4 m
2001593	MOLLELAST <sup>®</sup> haft loose in big box	8 cm x 4 m
2001594	MOLLELAST <sup>®</sup> haft loose in big box	10 cm x 4 m
2001595	MOLLELAST <sup>®</sup> haft loose in big box	12 cm x 4 m
2001597	MOLLELAST <sup>®</sup> haft loose in big box	8 cm x 20 m

## 2. Packaging, structure and composition

#### 2.1 Unit container

see 2.2

#### 2.2 Shelf container

REF 30063 – 30072; 109510; 82691; 82693; 82697; 82700: 1 piece (single packed) = 1 folding box made of cellulose

REF 2001591; 2001593 – 2001594; 2001597: loose in big box

## 2.3 Transit container

- corrugated cardboard box made of cellulose

REF	pieces
30063; 30065; 30066; 82693; 82697; 109510	120
30067; 82691; 82700;	100
30068; 30069; 30070; 30071; 30072	18
2001591	220
2001593	110
2001594	126
2001595	140
2001597	36

#### 3. Manufacture

Mollelast<sup>®</sup> haft are produced according to specification under hygienic conditions and packed as described in its relevant packaging specification.

#### 4. Description

Mollelast<sup>®</sup> haft is a manufactured using knitting technique with selvedge. It is cohesive. The product is non-sterile.

## 5. **Properties**

- o lengthwise elastic
- o widthwise elastic
- o cohesive because of latex particles
- o air-permeable
- o is not very bulky
- the turns of the bandage stay reliably in place
- o economical use of materials
- o high-quality, stable selvedges

#### 6. Intended purpose

For retention and for immobilization.

## 7. Medical device classification

Mollelast<sup>®</sup> haft is a medical device of class I according to rule 1 (according to directive 93/42/EEC and regulation (EU) 2017/45).

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

The starting materials used in the manufacture of Mollelast<sup>®</sup> haft 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<sup>®</sup> haft 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

We do not currently have any information on questionable ingredients.

## 10. Stability

Stored appropriately (keep dry, protected from dust and light) Mollelast <sup>®</sup> haft 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.

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