# Lomatuell® H
## Paraffin Gauze Dressing, hydrophobic, sterile

REF 23314 – 23318

November 2018

### 1. Composition of the product

Lomatuell® H paraffin gauze dressing consists of a net-like tulle made from cotton and impregnated with white paraffin.
The wound dressing is covered on both sides with glassine paper.

This product data sheet covers the following item:

| REF | Product description | Size |
|---|---|---|
| 23314 | Lomatuell® Paraffin Gauze Dressing, hydrophobic, sterile | 5 x 5 cm |
| 23315 | Lomatuell® Paraffin Gauze Dressing, hydrophobic, sterile | 10 x 10 cm |
| 23318 | Lomatuell® Paraffin Gauze Dressing, hydrophobic, sterile | 10 x 10 cm |
| 23316 | Lomatuell® Paraffin Gauze Dressing, hydrophobic, sterile | 10 x 20 cm |
| 23317 | Lomatuell® Paraffin Gauze Dressing, hydrophobic, sterile | 10 x 30 cm |

### 2. Packaging, structure and composition

### 2.1 Unit container

1 piece = 1 peel pouch
consisting of polyester, polyethylene and cellulose

### 2.2 Shelf container

1 Folding box consist of cellulose, instructions for use (cellulose)

| REFs | pcs. |
|---|---|
| 23314 - 23317 | 10 |
| 23318 | 50 |

## 2.3 Transit container

1 corrugated cardboard box (cellulose)

| REF | pcs. | Folding boxes |
|---|---|---|
| 23314 | 360 | 36 |
| 23315 | 120 | 12 |
| 23318 | 450 | 9 |
| 23316 | 120 | 12 |
| 23317 | 80 | 8 |

## 3. Manufacture

Lomatuell® H paraffin gauze dressing is produced according to specification in hygienic conditions and packed as described in its relevant packaging specification. The product is sterilized by radiation according to DIN EN ISO 11137 part 1-3.

## 4. Description

Lomatuell® H paraffin gauze dressing is used of the treatment of skin donor sites, leg ulcers, decubitus ulcers, burns, cuts, abrasions.
The product is available in various sizes.

## 5. Properties

Lomatuell® H paraffin gauze dressing is a knitted wide-mesh tulle with a water-resistant ointment base that does not stick to the wound. An even ointment distribution on the tulle must be ensured.

Lomatuell® H paraffin gauze dressing is for single use only and must not be resterilized.

The product is sterile as long as the package remains unopened and undamaged.

## 6. Intended purpose (please see valid instructions for use)

Lomatuell® H paraffin gauze dressing is intended to be used for the treatment of skin donor sites, leg ulcers, decubitus ulcers, burns, cuts and abrasions.

## 7. Medical device classification

Lomatuell® H paraffin gauze dressing is a medical device of Class IIb in terms of Rule 4.
(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 Lomatuell® H paraffin gauze dressing are safe if 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 Lomatuell® H paraffin gauze dressing 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 – do not store above 25°C – Lomatuell® H paraffin gauze dressing 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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Director Global Portfolio Management