

## Dauerbinde® F - Long stretch bandage

REF 105912 – 105918, 105990, 105991

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### 1. Composition of the product

The Dauerbinde® F consist of:

- Cotton 63 %
- Polyamide 28 %
- Elastane 9%

The bandage clips consist of:

- Metal parts: pure aluminium, with polyester varnish
- Elastic parts: core Lycra
- winding: polyester creme

The end of the bandages are fixed with a thermal transfer label.

- Thermal transfer label: silicone, polyurethane varnish, UV varnish, colour pigments and adhesive layer of copolyamides and binder.

This product data sheet applies to the following items:

| REF    | Product           | Size (stretched)<br>W x L | Bandage<br>clips | Packaging                             |
|--------|-------------------|---------------------------|------------------|---------------------------------------|
| 105914 | Dauerbinde® F     | 6 cm x 7 m                | 2                | packed individually<br>in folding box |
| 105916 | Dauerbinde® F     | 8 cm x 7 m                | 2                | packed individually<br>in folding box |
| 105915 | Dauerbinde® F     | 10 cm x 7 m               | 2                | packed individually<br>in folding box |
| 105991 | Dauerbinde® F V2D | 10 cm x 7 m               | 2                | packed individually<br>in folding box |
| 105917 | Dauerbinde® F     | 12 cm x 7 m               | 2                | packed individually<br>in folding box |
| 105990 | Dauerbinde® F V2D | 12 cm x 7 m               | 2                | packed individually<br>in folding box |
| 105912 | Dauerbinde® F     | 8 cm x 7 m                | 2                | lose in bulk                          |
| 105918 | Dauerbinde® K     | 10 cm x 7 m               | 2                | lose in bulk                          |
| 105913 | Dauerbinde® K     | 12 cm x 7 m               | 2                | lose in bulk                          |

## 2. Packaging, structure and composition

### 2.1 Unit container

see 2.2

### 2.2 Shelf container

1 folding box (cellulose), with instructions for use (cellulose)

### 2.3 Transit container

1 corrugated cardboard box, made of cellulose:

| REF                    | Pieces | Folding boxes |
|------------------------|--------|---------------|
| 105914, 105917, 105990 | 60     | 60            |
| 105916                 | 88     | 88            |
| 105912                 | 70     | 7             |
| 105915, 105991         | 95     | 95            |
| 105913                 | 120    | 12            |
| 105918                 | 140    | 14            |

## 3. Manufacture

The Dauerbinde® F is produced according to specification in hygienic conditions and packed as described in their relevant packaging specification.

## 4. Description

The Dauerbinde® F is a cream coloured, densely woven, permanently elastic bandage. The bandages are woven in rib weave and are rolled onto themselves. They are available in various widths. The Dauerbinde® K has a extensibility of approximately 160%. The bandages are used as supporting and pressure-relieving dressings for ligaments and joints.

## 5. Properties (see also valid instructions for use)

The Dauerbinde® F is a long-stretch/strong compression bandages with a distinctive textile structure. The bandages long-stretch quality allows the application of varying degrees of compression. The bandages conform well to the body, are not very bulky and are both sturdy and easy to clean. Because long-stretch bandages have a high resting pressure, they must be removed when the patient is resting and at night.

The Dauerbinde® F can be sterilized by steam or ethylene oxide in compliance with DIN EN ISO 17665-1 and DIN EN ISO 11135-1, respectively.

After sterilization with moist heat it is possible that the parameters "length stretched" and "elongation lengthwise" are changing.

The bandages can be washed with a mild detergent up to 10 times at 95 C °. Spread out the bandage to dry it.

Due to washing the lengthwise stretch can become higher.

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 (please see valid instructions for use)**

For immobilization of body parts, fixation of dressings and compression.

## **7. Medical device classification**

The Dauerbinde® F is a 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 the Dauerbinde® F are safe when the product is used appropriately and for the intended purpose.

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 Dauerbinde® F and that they are designed, manufactured and packaged in such a way that they 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, the Dauerbinde® F 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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