

DAUERBINDE® K GELENKVERBAND K

REF 22000 – 22004, 22007 – 22008 REF 22020 – 22024, 22050 – 22052 REF 34301 – 34303

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1. Composition of the product

DAUERBINDE® K and GELENKVERBAND K consist of:

- Cotton
- Polyamide
- Elastane (polyurethane)

The bandage clips consist of:

- metal parts: aluminium

- elasticated parts: - core of elastodiene (natural latex free)

- covered in: polyester

Fixation of the bandages ends: polyurethane dispersion (free of natural latex)

This product data sheet applies to the following items:

REF	Product	Size		Packaging
22000	Dauberbinde® K	6 cm x 7 m	stretched	loose in carton
22001	Dauberbinde® K	8 cm x 7 m	stretched	loose in carton
22002	Dauberbinde® K	10 cm x 7 m	stretched	loose in carton
22003	Dauberbinde® K	12 cm x 7 m	stretched	loose in carton
22004	Dauberbinde® K	20 cm x 7 m	stretched	loose in carton
22007	Dauberbinde® K	10 cm x 14 m	stretched	loose in carton
22008	Dauberbinde® K	12 cm x 14 m	stretched	loose in carton
34301	Dauberbinde® K V2D	8 cm x 7 m	stretched	loose in carton 10 pcs.
34302	Dauberbinde® K V2D	10 cm x 7 m	stretched	loose in carton 10 pcs.
34303	Dauberbinde® K V2D	12 cm x 7 m	stretched	loose in carton 10 pcs.

REF	Product	Size		Packaging
22020	Dauberbinde® K	6 cm x 7 m	stretched	loose in carton 10 pcs.
22021	Dauberbinde® K	8 cm x 7 m	stretched	loose in carton 10 pcs.
22022	Dauberbinde® K	10 cm x 7 m	stretched	loose in carton 10 pcs.
22023	Dauberbinde® K	12 cm x 7 m	stretched	loose in carton 10 pcs.
22024	Dauberbinde® K	20 cm x 7 m	stretched	loose in carton 10 pcs.
22050	Gelenkverband K	6 cm x 7 m	stretched	loose in carton
22051	Gelenkverband K	8 cm x 7 m	stretched	loose in carton
22052	Gelenkverband K	10 cm x 7 m	stretched	loose in carton

Gelenkverband K represents a shorter version of Dauerbinde® K and is intended for support and relief in the joint area.

2. Packaging, structure and composition

2.1 Unit container

- see 2.2

2.2 Shelf container

- folding box (cellulose)
 (exc. REF 22007 and 22008 → wrapping cover made of polypropylene)
 instructions for use (cellulose)
- 2.3 Transit container

- corrugated cardboard box

3. Manufacture

DAUERBINDE® K and GELENKVERBAND K are produced according to specification in hygienic conditions and packed as described in their relevant packaging specification.

4. Description

The bandages are woven in rib weave and are rolled onto themselves. They are available in various widths and lengths. They are extensible by approximately 180 %. The end is fixed onto the bandage head with bandage clips.

5. Properties

DAUERBINDE® K and GELENKVERBAND K are long-stretch/strong compression bandages with a distinctive textile structure. The bandages long-stretch quality allows the application of varying degrees of compression.

Highly elastic, the bandages can be applied fold-free to exposed places such as the heel. The bandage is supple, hard-wearing and easy to wash. DAUERBINDE® K and GELENKVERBAND K can be washed and sterilized by steam in compliance with DIN EN ISO 17665-1.

The bandages can washed by 10 x 40 C ° and washed with a mild detergent. The machine drying is possible.

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)

DAUERBINDE® K and GELENKVERBAND K are intended to be used for the immobilization of parts of the body, for dressing retention and for compression.

7. Medical device classification

DAUERBINDE® K and GELENKVERBAND K 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 the DAUERBINDE® K and GELENKVERBAND K 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® K and GELENKVERBAND K 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 – at a temperature not exceeding 30° C and a relative humidity not exceeding 70 % - DAUERBINDE® K and GELENKVERBAND K have a shelf life of 5 years.

10. Disposal

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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 D-56579 Rengsdorf signed by Dr. Martin Abel (Medical & Regulatory Affairs)