

NOBAMED Paul Danz AG

UNIVERSALBINDE

in Folie

REF 431515

Product Description, Intended use, Application

The light, white medium stretch bandage is **15 cm wide and 5 m long** (in stretched condition). It has overlock seams and woven edges. Owing to its material and its weave, it is universally applicable in all medical fields. The rolled bandage is for single use only.

Composition

Polyester, elastane, cotton

Contra-Indications

The product should not be used in the case of a known allergy against the material.

Notes

Please ensure after application, that the bandage must neither cause pressure sores, strangulation marks nor pains, numbness and circulatory disorders.

The product has been subjected to a validated microbial reduction process and is therefore pre-sterilized.

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Regulative Requirements, Common Standards

Medical device according to the MDD 93/42/EEC and MDR (EU) 2017/745. The product does not contain dangerous toxic substances according to REACH.

Packaging

Primary packaging: PP foil

Secondary packaging: folding box

made of cellulose

Tertiary packaging: carton made of

cellulose

Symbols used in labelling

Explanations at www.nobamed.com







Marking on all packaging levels with CE and according to DIN EN ISO 15223-1 and ISO 20417.

Storage and Transport

To be stored in a dry and dust-free environment

Single use device

Reusing a single use medical device can lead to microbiological danger. Reprocessing, for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.

Product Data Sheet: September 14, 2021 [REV 6] replaced: April 01, 2020 [Rev 5]