

NOBAMED Paul Danz AG

NOBATEL[®]

in foil

REF 426506

Product Description, Intended use, Application

The white, size **6 cm x 5 m** (stretched length) bandage, is a light short-stretch bandage with a stretchability of $60 \pm 15\%$. It has overlock seams and woven edges. NOBATEL[®] is universally applicable in all medical fields. The rolled bandage is for single use only and is individually packed.

Composition

Polyester, cotton (overlock seams, woven edges)

Contraindications

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

Note

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:

Secondary packaging:

OPP foil

folding box made of cellulose

Tertiary packaging:

carton made of cellulose

Symbols used in labelling Explanations at <u>www.nobamed.com</u>



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.