

## NOBAMED Paul Danz AG

## **NOBATEL®**

in foil

#### REF 426512

## Product Description, Intended use, Application

The white, size 12 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

The product does not contain dangerous toxic substances according to REACH.

### **Packaging**

Primary packaging: OPP foil

Secondary packaging: folding box

made of cellu-

lose

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 environ-

#### 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 13, 2021 [REV 4] replaced: April 01, 2020 [Rev 3]