

NOBAMED Paul Danz AG

NOBAFIX®-steril

REF 731106

Product Description, Intended use, Application

This fixation bandage with a width of 6 cm and a stretched length of 4 m is a rolled, lengthwise-elastic dressing retention bandage. Due to its weave, the bandage has a fine, smooth and tight structure. The elastic bandage is used to fix wound pads, especially over joints and body curves. As a damp bandage, NOBAFIX® is also used to shape and/or fix plaster splints and cast dressings. NOBAFIX®-steril is for single use.

Composition

Polyester

Contra-Indications

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

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.

Sterilization of the product complies with DIN EN ISO 11135.

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

Packaging

Primary packaging: paper-foil-

packaging

Secondary packaging: folding box

made of cellulose

Tertiary packaging: carton made of cellulose

Symbols used in labelling

Explanations at www.nobamed.com









C€

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

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

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: August 03, 2021 [REV 6] replaced: May 11, 2020 [Rev 5]