



NOBAMED Paul Danz AG

RUDAFIX[®]

REF 070182

Product Description, Intended use, Application

The hypoallergenic fixation tape (2.50 cm x 9.14 m, with side discs) is made of a transparent, perforated film and is coated with a polyacrylate adhesive. The fixation tape is easy to tear both crosswise as well as lengthwise and is suited for the fixation of wound pads, bandage dressings, tubes and catheters.

Composition

Polyethylene, polyacrylate adhesive

Contraindications

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

Notes

To avoid swelling and circulatory disorders, fixation tapes are not applied on the extremities under tension in a circular way.

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 Legal Requirements

RUDAFIX[®] is a medical product according to directive MDD 93/42/EEC and the regulation MDR (EU) 2017/745.

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

Packaging

Primary packaging: folding box made of cellulose

Secondary 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 DIN EN 1041.

Storage and transport

To be stored in a dry and dust-free environment, protected against sunlight.

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.