



NOBAMED Paul Danz AG

RUDASILK®

REF 070595

Product Description, Intended use and Application

The hypoallergenic fixation tape, 5,00 cm x 9.14 m, on a roll without side discs, is made of artificial silk covered with polyacrylate adhesive.

It is suitable for the fixation of wound pads, bandage dressings, tubes and catheters.

Composition

Artificial silk, 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 Regulatory Requirements, Common Standards

Medical Device according to MDD 93/42/EEC, MDR (EU) 2017/745.

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

It complies with the DIN EN ISO 10993-5 and -10.

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 ISO 20417

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.