

NOBAMED Paul Danz AG

RUDAPOR®

REF 070491

Product Description, Intended use, Application

The hypoallergenic fixation tape, 1.25 cm x 9.14 m on a roll without side discs, is made of white paper covered with polyacrylate adhesive.

RUDAPOR® is suited for the fixation of wound pads and bandage dressings.

Composition

Cellulose, polyester, poyacrylate adhesive

Contraindications

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

Residual risks, undesirable side effects, warnings

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

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

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 MDD 93/42/EEC, 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

Dry and dustfree.

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: May 03, 2021 [Rev6], replaces: May 29, 2020 [Rev5]