



NOBAMED Paul Danz AG

RUDATUBIX®

REF 069314 (as of LOT 137663)

Product Description, Intended use, Application

RUDATUBIX® (3.5 x 9 cm) is a disposable fixation plaster for tubes. It is universal, breathable and gentle to the skin. Tubes, probes, catheters and drainage tubes can be securely fastened by means of adhesion and velcro type fastening. The advantage of the velcro type fastening is that the position of the medical device can be repeatedly controlled. Its use is recommended for tubes and feed lines with a diameter of 3-8 mm. The product is individually packed.

Composition

Polyurethane, Viscose, Polypropylene, Acrylic fibers
Acrylate adhesive

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 MDD 93/42/EEC, MDR (EU) 2017/745.

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

Packaging

Primary	PE bag
Secondary:	PE bag
Tertiary:	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, protect from 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.