



NOBAMED Paul Danz AG

RUDATUBIX®

REF 069314 (as of LOT 138359)

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 MDR (EU) 2017/745.

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

Packaging

Primary packaging	paper-paper-packaging
Secondary packaging:	folding box made of cellulose
Tertiary 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

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.