



NOBAMED Paul Danz AG

FIXIERGURT

REF 374650

Product Description, Intended use, Application

The padded fixation belt (5 cm x 6 m) is made of foam which is covered with a cotton tube. It can be used to make traditional figure-of-eight bandages or arm slings.

Composition

Cotton, polyurethane, polyamide

Contraindications

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 Legal Requirements

Medical product according to the 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:	folding box made of cellulose
Secondary:	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 ISO 20417.

Storage and Transport

Dry and dust free

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.