

NOBAMED Paul Danz AG

RUDALASTIK®

REF 095506

Product Description, Intended use, Application

The longitudinal elastic plaster bandage (width: 6 cm, unstretched length: 2.5 m) is coated with a hypoallergenic adhesive. The adhesive layer does not impair the open-pored structure of the bandage. RUDALASTIK[®] stabilizes and compresses muscles, tendons and joints and is in most cases used together with RUDATAPE[®] for the application of functional bandages. In phlebology, RUDALASTIK[®] is used as a compression in cases of venous insufficiency.

Composition

Cotton, polyacrylate adhesive

Contraindications

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

Residual Risks, Undesirable Side Effects, Warnings, Notes

In the case of a medical compression therapy the contra-indications and risks mentioned in the relevant medical guidelines must be observed.

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

Explanation at <u>www.nobamed.com</u>



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.