

NOBAMED Paul Danz AG

# **RUDANAHT®**

## **REF 061225**

## Product Description, Intended use, Application

Reliably adhesive and elastic, beige-coloured wound suture strips, **size 25 mm x 100 mm**, packed per **4 pieces** in sterile packaging. The wound suture strips are used for an atraumatic primary closure of small, smooth, superficial lacerations or cuts, surgical incisions, as a complement to/relief for subcutaneous and intra-cutaneous sutures or for wounds that have been closed with staples, for the fixation of skin grafts, and if staples and sutures are prematurely removed. RUDANAHT<sup>®</sup> are for single use only.

## Composition

Polyamide, polyester, polyacrylate adhesive

## **Contra-Indications**

Wounds under tension, infected wounds, deeper wounds, and heavily bleeding wounds should not be closed with wound suture strips.

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

## Note

RUDANAHT<sup>®</sup> is not intended for the fixation of e.g., dialysis cannulae.

#### **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*.

Sterilization of the product complies with DIN EN ISO 11135.

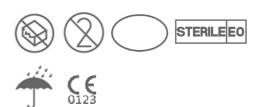
The product does not contain dangerous toxic substances according to REACH.

## Packaging

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

## Symbols used in labelling

Explanation 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

## **Sterile device**

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

#### 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.