NOBAMED Paul Danz AG

# RUDANAHT®

## REF 061012

### Product Description, Intended use, Application
Reliably adhesive and elastic, beige-coloured wound suture strips, **size 13 mm x 100 mm**, packed per **6 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® 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® 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
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| Primary packaging: | paper-film-packaging |
| Secondary packaging: | folding box made of cellulose |
| Tertiary packaging: | 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.