



NOBAMED Paul Danz AG

NOBATAMP®-steril

REF 631105 (as of LOT 135971)

Product Description, Intended use, Application

The **sterile** ribbon gauze strip (5 cm x 5 m) is individually packed and made of cotton. It serves as tamponade or drainage in wound cavities and fistula tracts. It is likewise suited for use in natural body openings (for example pharyngeal space). They are for single use only. NOBATAMP-steril are absorbent, tearproof and air permeable.

Composition

Cotton

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 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.

The ribbon gauze strips are verified with the DIN EN 14079

Sterilization of the product complies with DIN EN ISO 11135.

Packaging

Primary packaging:	paper-film-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.

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.