

## NOBAMED Paul Danz AG

# **NOBACERVIX®-sterile net wadding**

## REF 872406 (as of LOT 138438)

# **Product Description, Intended use, Application**

The sterile, **cylindrical** tampon, **size 3.8 cm in diameter**, has a filling of absorbent, pressed cotton wool and a fine knit tubular wrapping. The extension of the knitted wrapping serves as a return strap. The tampon is suited for wound care in the case of gynaecological surgery. NOBACERVIX®-steril is for single use only and is individually sealed.

## 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 MDR (EU) 2017/745.

Verification of the cotton for identity and purity using the tests from DIN EN 14079.
Testing of the absorption capacity using the tests from USP purified cotton.

Sterilization complies with DIN EN ISO 11135.

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

## **Packaging**

Primary packaging: Secondary packaging:

paper-film-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.