



NOBAMED Paul Danz AG

NOBACERVIX[®] net wadding

REF 872302 (as of LOT 138885)

Product Description, Intended use, Application

The **cylindrical** tampon of **2 cm size** 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[®] is for single use only.

Composition

Cotton

Contraindications

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

Note

The product must be sterilized in accordance with a validated sterilization method before use on open wounds. The product can be sterilized with moist heat at 121°C/ 134°C, 2 to 3 bar, according to DIN EN 17665, radiation according to DIN EN ISO 11137 or ethylene oxide according to DIN EN ISO 11135.

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*.

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.

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

Packaging

Primary packaging: PE-bag

Secondary 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

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.