



NOBAMED Paul Danz AG

NOBACERVIX[®] gauze wadding

REF 872108 (as of LOT 137309)

Product Description, Intended use, Application

The **round-shaped** tampon of **6.5 cm size** has an absorbent cotton core and a gauze wrapping. It 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*.

The tampon is tested according to DIN EN 14079 and USP/BP standards for 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.