

NOBAMED Paul Danz AG

NOBACERVIX®-steril gauze wadding

REF 872006 (as of LOT 138738)

Product Description, Intended use, Application

The sterile, round-shaped tampon of 6 cm size has an absorbent cotton core and a gauze wrapping. It is suited for wound care in the case of gynaecological surgery. NOBACERVIX[®]-steril is for single use only and is individually sealed and packed.

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:	paper-film-packaging
Secondary packaging:	folding box made of cellulose
Tertiary packaging:	carton made of cellulose

Symbols used in labelling

Explanation at <u>www.nobamed.com</u>



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.