



**NOBAMED Paul Danz AG**

## **NOBACERVIX<sup>®</sup> gauze wadding**

**REF 872101 (as of LOT 138885)**

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

The **round-shaped** tampon of **3 cm size** has an absorbent cotton core and a gauze wrapping. It is suited for wound care in the case of gynaecological surgery. NOBACERVIX<sup>®</sup> 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 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](http://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.