

# **NOBAMED Paul Danz AG**

## **MULLTUPFER-steril**

#### **REF 735533**

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

The sterile gauze balls have a diameter of 4.0 cm. The gauze (DIN EN 14079 type 20) is looped into a round shape. They are used for the treatment of superficial wounds and for skin disinfection. One sterile pouch contains 5 gauze balls.

### Composition

Cotton, silicone ring

#### **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 MDD 93/42/EEC, MDR (EU) 2017/745.

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

The gauze complies with the requirements of DIN EN 14079 type 20.

Sterilization complies with DIN EN 11135.

### **Packaging**

Primary packaging:

film/paper packaging

Secondary packaging:

folding box made of cellulose

Tertiary packaging:

Carton made of cellulose

### Symbols used in labelling

Explanations at www.nobamed.com









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Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and ISO 20417.

### **Storage and Transport**

Dry and dust free.

### 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.