

**NOBAMED** Paul Danz AG

# **MULLTUPFER-steril**

## **REF 735550**

# Product Description, Intended use, Application

The sterile gauze balls have a diameter of 5 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:

Secondary packaging:

Tertiary packaging:

Carton made

film/paper

packaging

folding box

made of

cellulose

## Symbols used in labelling

Explanations at www.nobamed.com



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.

Product Data Sheet: June 22, 2021 [Rev 5], replaces: July 25, 2018 [Rev 4]