



MULLTUPFER

REF 877012

Product Description, intended use, application

The gauze balls have a diameter of 2.0 cm. The gauze (DIN EN 14706 type 20) is twisted into a round shape without using any rubber ring. They are used for the treatment of wounds and for skin disinfection. Prior to these activities, the product has to be sterilized with a validated procedure (moist heat at 121°C / 134°C, 2 to 3 bar, according to DIN EN ISO 17665, radiation according to DIN EN ISO 11137 or ethylene oxide according to DIN EN ISO 11135).

Composition

Cotton

Note

Sterilize before use

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 Legal Requirements

MULLTUPFER (gauze ball) is a medical product according to the directive 93/42/EEC and the regulation MDR (EU 2017/745).

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

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

Date of Information: May 18, 2021[Rev 5]
replaced: April 01, 2020 [Rev 4]

Packaging

Primary packaging: PE-bag

Secondary packaging: carton 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 DIN EN 1041.

Storage and Transport

Dry and dustfree

Single use device

Reusing a single use medical device can lead to microbiological danger. Re-processing, for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.

Storage

To be stored in a dry and dust-free environment