NOBAMED Paul Danz AG

MULLTUPFER-steril

REF 735420

Product Description, Intended use, Application

The sterile gauze balls have a diameter of 3.0 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 4 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

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.