



NOBAMED Paul Danz AG

NOBAMULL

REF 250250

Product Description, Intended use, Application

The dressing gauze, size **10 cm x 5 m**, is suited for the individual production of wound dressings and is thus used for wound treatment. NOBAMULL is **folded eight times to 10 cm**, rolled up and then packed in dispensers. It is for single use.

Composition

Cotton

Notes

NOBAMULL must be sterilized as a wound dressing by a validated procedure 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 the MDD 93/42/EEC and MDR (EU) 2017/745.

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

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

Packaging

| | |
|----------------------|------------------------------------|
| Primary packaging: | plastic recipient |
| Secondary packaging: | folded 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

To be stored in a dry and dust-free environment

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.