



NOBAMED Paul Danz AG

NOBAMULL

REF 250260

Product Description, Intended use, Application

The dressing gauze, size **10 cm x 10 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 Regulatory 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:	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

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.