



NOBAMED Paul Danz AG

MULLKOMPRESSEN

REF 863055

Product Description, Intended use, Application

Unsterilized packed gauze swab, **8-ply**, made of 17-thread dressing gauze, **size 5 cm x 5 cm, packed per 100 pcs**, with raw edges folded back. The gauze swab is used in primary wound care, for wound cleansing, wound covering, and for the absorption of blood and wound fluid. The gauze swab is for single use.

Composition

Cotton

Contra-Indications

The product should not be used in the case of a known allergy against the material.

Note

The product must be sterilized in accordance with a validated sterilization method 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 MDR (EU) 2017/745.

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

Packaging

Primary packaging: sterilizable paper pouch
Secondary packaging: carton made of cellulose

Symbols used in labelling

Explanation at www.nobamed.com



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN ISO 20417

Storage and Transport

Dry and dustfree

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.