



NOBAMED Paul Danz AG

KOMPRESSEN-steril

REF 712613

Product Description, Intended use, Application

Gauze swab, **12-ply**, made of 17 thread dressing gauze, **size 10 cm x 12.5 cm**, individually packed **per 10 pieces** in sterile packaging, 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 only.

Composition

Cotton

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 gauze slit swabs comply with the requirements of the DIN EN 14079.

Sterilization of the product complies with DIN EN ISO 11135.

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

Packaging

Primary packaging:	paper-paper-packaging	
Secondary packaging:	folding made of cellulose	box
Tertiary 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, protect from sunlight.

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.