



NOBAMED Paul Danz AG

SCHLITZKOMPRESSEN-steril

REF 751205

Product Description, Intended use, Application

Gauze slit swab, **12-ply**, made of 17 thread dressing gauze, **size 5 cm x 5 cm**, individually **packed per 2 pieces** in sterile packaging, with Y-cut. The gauze slit swab serves as a wound cover of inlets or outlets of probes, drainages, catheters, Kirschner's wire tractions or external fixators. The gauze slit 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 box made of cellulose
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.