

NOBAMED Paul Danz AG

MULLKOMPRESSEN

REF 857097

Product Description and Purpose

Unsterilized packed gauze swabs, 16-ply, made of 17-thread dressing gauze, size 9 cm x 7.5 cm, packed per 100 pcs, with raw edges folded back. The gauze swabs are used in primary wound care, for wound cleansing, wound covering, and for the absorption of blood and wound fluid. The gauze swabs are for single use and they must be sterilized before use on open wounds with a validated procedure (moist heat in compliance with DIN EN ISO 17665, radiation in compliance with DIN EN ISO 11137, or ethylene oxide in compliance with DIN EN ISO 11135).

Contra-Indications

No contra-indications known, unless there is an allergy attributable to cotton.

Composition

Cotton

Normative and Legal Requirements

MULLKOMPRESSEN are class I, rule 4, medical products according to the MDD, the directive 93/42/EEC and the MDR (EU 2017/745. The gauze swabs comply with the requirements of the DIN EN 14079.

According to the European standard EN ISO 10993-1 "Biological Evaluation of Medical Devices", gauze swabs are medical products in contact with the body surface (skin and mucous membrane), and they are classified with the duration of contact A (less than 24 h).

The product does not contain dangerous toxic substances according to REACH. It has CE marking and DIN EN ISO 15223-1 and EN 1041 labels on all its packaging.

Packaging

Primary packaging: sterilizable

paper pouch

Date of information: 02.02.2018 [REV 4]

replaced: 22.09.2015 [Rev 3]

Secondary packaging:

carton made of cellulose

Storage

To be stored in a dry and dust-free environment

The product bears the following labels and symbols



Sterilize before use