

### **REF 716710** (as of LOT 36305)

#### Contents of this procedure pack:

20 x gauze swabs, 10 x 10 cm, 16-ply NOBAMED Paul Danz AG, MDCE

## Product Description, Intended use, Application

The sterile procedure pack consists of 20 gauze swabs. The disposable gauze swabs with raw edges folded back are used for primary wound care, for wound cleansing, wound covering, and for the absorption of blood and wound fluid.

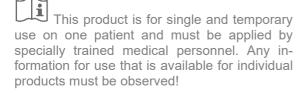
#### Composition

cotton

#### **Contra-Indications**

No contra-indications known.

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



#### **Normative and Legal Requirements**

Procedure Pack according to Art. 22, Medical Device Regulation (EU) 2017/745, risk class I

The compatibility of the customized medical devices or other products has been assessed with due regard for the indications of the respective manufacturers, and operations have been performed in accordance with the aforementioned indications.

The manufacturers' intended use is not changed.

The systems and procedure packs are packed in compliance with a validated procedure.

All activity is properly monitored and controlled as part of our QM system, in accordance with DIN EN ISO 13485

A validated sterilization process is used for sterile procedure packs, taking into account the manufacturers' instructions, so that product functionality and product safety of the components are maintained after a system or procedure pack has been compiled and sterilized.

# Sterilization and packaging are subject to supervision of our Notified Body TÜV Süd PS 0123 pursuant to Annex XI, Part A.

The gauze complies with the requirements of DIN EN 14079 type 17.

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

It has CE marking and DIN EN ISO 15223-1 labels on all its packaging

#### **Storage and Transport**

To be stored in a dry and dust-free environment, protect from sunlight.

## The product bears following labels and symbols

