NOBAMED Paul Danz AG

X-RAY MULLKOMPRESSEN

REF 820120

Product Description, Intended Use, Application
Non-sterile packed gauze swabs, **8 ply, pre-washed,** made of 17 thread dressing gauze, **size 10 cm x 20 cm**, **packed per 100 pcs**, with X-Ray thread applied in snake-shape, raw edges folded back. The gauze swabs are used for wound care in the OR area. They are used for absorbing blood and body fluids and for wound cleansing. The gauze swabs are Intended for single use only.

Composition
Cotton, bariumsulphate, PVC, DOTP

Contra-Indications
No contra-indications known.

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 *MDD 93/42/EEC, MDR (EU) 2017/745.*

The gauze swabs comply with the requirements of DIN EN ISO 14079.

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.