



NOBAMED Paul Danz AG

NOBATRAST®-Vakuum-OP-Set Mullkompressen

REF 612110

Product Description, Intended use, Application

Sterile double packed gauze swabs, **12-ply**, made of 17-thread dressing gauze, **size 10 cm x 10 cm, packed per 10 pcs**, with X-Ray thread, raw edges folded back. The disposable gauze swabs of the NOBATRAST®-Vacuum OR sets are used for wound care in the OR area, absorbing blood and body fluids and for wound cleansing. The gauze swabs are vacuum-packed in two transparent film-film packages. They are firmly positioned in the package. Owing to a blue counting card on the inner packaging, and a second blue counting card on the inner side of the outer packaging, the counting may be checked quickly and safely. The vacuum of the inner and outer packaging guarantees the sterility of the set until it is used.

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.

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 meet the requirements of DIN EN 14079.

Sterilization of the product complies with DIN EN ISO 11137.

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

Packaging

Primary packaging:	film-film-packaging
Secondary packaging:	film-film-packaging
Tertiary packaging:	folding box made of cellulose
Quaternary 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.