



NOBAMED Paul Danz AG

NOBATRAST®-Vakuum-OP-Set X-Ray Kompressen

REF 612120

Product Description and Purpose

Sterile double packed gauze swabs, **12-ply**, made of 17-thread dressing gauze, **size 10 cm x 20 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, for wound cleansing, wound covering, and for the absorption of blood and wound fluid. 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.

Contra-Indications

No contra-indications known, unless there is an allergy attributable to cotton. The X-Ray thread is firmly heat-bonded to the swab and folded inwards, so there is no direct contact with the soft tissue or organ tissue.

Composition

Cotton, bariumsulphate, PVC, DINP

Normative and Legal Requirements

NOBATRAST®-Vakuum-OP-Set X-Ray Kompressen is a class IIa, rule 7, medical product 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 from the outside (vascular system, indirect), and they are classified with the duration of contact A (less than 24 h). Sterilization of the product complies with DIN EN ISO 11137.

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

Storage

To be stored in a dry and dust-free environment, protected against direct sunlight.

The product bears the following labels and symbols

