



NOBAMED Paul Danz AG

NOBATRAST® OP-Set Bauchtuch

REF 609544 (as of LOT 140055)

Product Description, Intended use, Application

Double packed, sterile, **green lap sponges** made of cotton gauze 20 threads, **6 layers, pre-washed, size 45 cm x 45 cm, without loop** and with **X-Ray chip**. The disposable lap sponge is used for wound care in the OR area, for wound covering, for the absorption of blood and wound fluid and to keep back and hold organs and body tissues. The counting cards on the sterile packaging are removable, self-adhesive and allow quick and safe counting control.

Composition

Cotton, bariumsulphate, PVC, DOTP

Contraindications

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 MDR (EU) 2017/745

The lap sponges comply with the requirements of the DIN EN 14079.

Sterilization of the product complies with DIN EN ISO 11135.

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

Packaging

Primary packaging: paper wrap

Secondary packaging: paper-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

Medical devices labelled in accordance with MDR (EU) 2017/ 745 bear a human-readable manufacturing and/or expiry date on the packaging, within which the device can be used safely.

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.