



**NOBAMED Paul Danz AG**

## **NOBATRAST®-OP-Set Bauchtuch**

**REF 608544 (as of LOT 136714)**

### **Product Description, Intended use, Application**

Sterile double packed **blue lap sponges** made of cotton gauze 20 threads, **6 layers, pre-washed, size 45 cm x 45 cm, with loop, with X-Ray thread**. 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 card in the sterile packaging allows quick and safe counting control.

### **Composition**

Cotton, bariumsulphate, PVC, DOTP

### **Contraindications**

No contraindications 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 Regulatory Requirements, Common Standards**

Medical Device according to MDD 93/42/EEC, MDR (EU) 2017/745

The lap sponges comply with the requirements of the DIN EN ISO 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](http://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.