



**NOBAMED Paul Danz AG**

## **NOBATRAST® OP-Set Präpariertupfer**

**REF 645608** (as of LOT 135255)

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

The double packed preparation balls made of 24-thread dressing gauze, 8 cm x 8 cm, (size M), packed per 10 pcs, have a woven-in X-ray thread. They are used to prepare delicate tissue in the surgical field (for example blood vessels, fine tendons).

Owing to a counting card on the inner packaging and a second counting card on the outer packaging, the counting may be checked quickly and safely.

### **Composition**

Cotton, X-Ray-thread contains barium sulfate, polypropylene

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

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

The gauze complies with the requirements of DIN EN 14079 type 24.

Sterilization of the product complies with DIN EN ISO 11135.

### **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**

Explanations at [www.nobamed.com](http://www.nobamed.com)



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and 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.