

NOBAMED Paul Danz AG

NOBATRAST[®]-Vakuum-OP-Set Tupfer

REF 635615

Product Description and Purpose

The double packed gauze balls, diameter 2.5 cm, are made of 20-thread dressing gauze and have a woven-in X-ray thread. The gauze is twisted into a round shape without using any rubber ring. The set contains 10 gauze balls. They are used to absorb blood and secretion in the operative area and to clean the operation wound from blood and secretion. The balls are separately placed in a transparent tray, thus enabling a visual content check before the operation. Owing to a counting card on the inner packaging and a second counting card on the inner side of the outer packaging, the counting may be checked guickly and safely. The vacuum of the inner and outer packaging guarantee the sterility of the set until it is used.

Contraindications

Allergy against cotton, barium sulfate, PVC or DINP

Composition

Cotton, X-Ray-thread contains barium sulfate, PVC, DINP

Normative and

Legal Requirements

NOBATRAST[®]-Vakuum-OP-Set Mulltupfer (vacuum OP set gauze balls) is a medical product according to the MDD 93/42/EEC and the MDR (EU) 2017/745 and is classified as class IIa, rule 7.

The gauze complies with the requirements of DIN EN 14079 type 20.

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 labels on all its packaging.

Date of information: May 02, 2018 [REV 4] replaced: September 25, 2015

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 symbols and marking:

