



NOBAMED Paul Danz AG

NOBATRACHEAL[®]-steril

REF 874300

Product Description, Intended Use, Application

NOBATRACHEAL[®]-steril is a swab with Y-cut, size **8 cm x 10 cm** and provided with a punched hole. It can therefore be used for hole diameter of 12-17 mm or rather for tracheostomy tubes with an outside diameter of 31–50 Charrière (Ch). The sterile, aluminium-coated, and thereby non-adhesive tracheal swab with humidity barrier is used for the outlet of tracheostomy tubes in cases of tracheostoma. NOBATRACHEAL[®]-sterile is for single use only and individually packed.

Composition

Polyethylen, aluminium, polyester, rayon

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 Regulatory Requirements, Common Standards

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

Sterilization of the product complies with DIN EN 11135.

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

Packaging

Primary packaging: paper-paper packaging

Secondary packaging: folding box made of cellulose

Tertiary 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

Storage and Transport

Dry and dust-free

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact. (Abschnitt bei Bedarf)

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