

NOBAMED Paul Danz AG

GEHÖRGANGTUPFER

REF 875010

Product Description, Intended use, Application

The auditory meatus swab (size M, length: 9 cm) is a twisted swab, which is suitable for application during treatments of the ear due to its pointed shape. The ear canal swab is made of cotton gauze which complies to standard EN 14079 type 20. Before use on the ear, the product must be sterilised using a validated method.

Composition

Cotton

Contraindications

The product should not be used in the case of a known allergy against the material.

Notes

Sterilize before use

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

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

Packaging

Primary: folding box

made of cellulose

Secondary: carton

made of cellulose

Symbols used in labelling

Explanations 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 dustfree

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.