

NOBAMED Paul Danz AG

X-RAY GEHÖRGANGTUPFER

REF 875115

Product Description and Purpose

The twisted auditory meatus swab, size L, 14 cm in length, packed per 100 pcs, is provided with a woven-in X-ray thread and, due to its pointed shape, is suited for ear operation. In the area of the auditory canal, its pointed shape is especially of advantage. Before use in surgery, the product must be sterilized with a validated procedure (moist heat at 121°C/134°C, 2 to 3 bar, in accordance with DIN EN ISO 17665, radiation in accordance with DIN EN ISO 11137, or ethylene oxide in accordance with DIN EN ISO 11135).

Contraindications

Allergy against cotton, barium sulfate, PVC or DINP

Composition

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

Normative and Legal Requirements

X-RAY GEHÖRGANGTUPFER (X-Ray auditory meatus swab) is a medical product according to the MDD 93/42/EEC and the MDR (EU) 2017/745 and is classified as class IIa, rule 5.

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

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

It has DIN EN ISO 15223-1 labels on all its packaging.

Date of information: April 16, 2018 [REV 6]

replaced: September 24, 2015

Packaging

Primary packaging: folding box

made of cellulose

Secondary packaging: carton made of

cellulose

Storage

To be stored in a dry and dust-free environment

The product bears the following symbols and marking:







Sterilize before use