



OHRENKOMPRESSE

REF 874950

Product Description, Intended use, Application

The disposable product OHRENKOMPRESSE is a non-sterile, sickle-shaped swab made of binderless non-woven. In sterile condition it is used as wound cover for wound care in the case of ear operations where stitched wound lies behind ear lobe. The swab can also be used as padding behind the ear lobe.

Composition

Viscose, polyester

Contra-Indications

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

Note

The product must be sterilized in accordance with a validated sterilization method before use on open wounds. The product can be sterilized with moist heat at 121°C/ 134°C, 2 to 3 bar, according to DIN EN 17665, radiation according to DIN EN ISO 11137 or ethylene oxide according to DIN EN ISO 11135.

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 non-woven is tested according to DIN EN 1644-1 and -2.

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

Packaging

Primary packaging: folding box made of cellulose

Secondary packaging: 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

To be stored in a dry and dust-free environment

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.