



NOBAMED Paul Danz AG

NOBATOP[®]-steril 12

REF 706610

Product Description and Purpose

Sterile non-woven swab, binder-free, **6-ply**, **size 10 cm x 10 cm**, individually **packed per 10 pieces**, packed in a folding box with convenient dispenser opening. The swab is used in general wound care, for wound cleansing, wound covering, and for the absorption of blood and wound fluid. The swab is for single use only. NOBATOP[®]-steril 12 is absorbent, air-permeable, soft and therefore gentle to the skin.

Composition

Viscose, polyester

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 Regulative Requirements, Common Standards

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

The swab is verified with the DIN EN 1644-1 und -2.

Sterilization of the product complies with DIN EN ISO 11135.

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

Packaging

Primary packaging: paper-film-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 dustfree

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

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.