



NOBAMED Paul Danz AG

NOBATOP[®]-S

REF 855005

Product Description, Intended use, Application

Non-sterile, non-woven swab with Y-cut, binder-free, 6-ply, size 5 cm x 5 cm, packed per 100 pieces in a paper pouch. The slit swab is used in general wound care, for wound cleansing, wound covering, and for the absorption of blood and wound fluid. Especially for wound care during drainage, tracheotomies and extensions as well as for protection/covering during cannula and tube applications. NOBATOP[®]-S is absorbent, air-permeable, soft and therefore gentle to the skin. The slit swab is for single use only.

Composition

Viscose, polyester

Contraindications

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

Notes

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 MDR (EU) 2017/745.

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

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

Packaging

Primary packaging: paper-pouch

Secondary 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

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.