

NOBAMED Paul Danz AG

NOBALINE®-steril

REF 770111

Product Description, Intended use, Application

NOBALINE®-sterile, 10 cm x 12 cm, is an aluminium-coated wound swab, made of nonwoven, which does not adhere to the wound. Owing to the porous structure of the aluminium layer, the wound secretions are rapidly passed to the swab's absorbent core. The sterile wound swab is used to cover superficial, lightly secreting or drying wounds, painful wounds e.g. skin abrasions and cuts. NOBALINE®-sterile is for single use only and is individually packed in sterile packaging.

Composition

Polyethylene, aluminum, polyester, rayon

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.

Sterilization of the product complies with DIN EN 11135.

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

Packaging

Primary packaging: paper-paper

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.

Product Data Sheet: September 13, 2022 [REV 5] replaces: September 25, 2015 [REV 4]