NOBAMED Paul Danz AG

NOBALINE®-Betttuch

REF 772580

Product Description, Intended use, Apllication
NOBALINE®-Betttuch is an **80 cm x 250 cm** aluminium-coated non-woven bed sheet that is non-adhesive to wounds. The sterile bed sheet is mainly used as an underlay for the treatment of large wounds and abrasions in intensive care. The NOBALINE®-Betttuch can be used as an overlay for normal beds as well as for special beds. NOBALINE®-Betttuch is intended for single use and is individually sealed.

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-film packaging

Secondary packaging: PE-bag

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.