NOBAMED Paul Danz AG

NOBADERM®

REF 160607 (as of LOT 136997)

Product Description, Intended use, Application

NOBADERM® (6 x 7 cm) is a sterile, transparent film dressing. It is made of polyurethane and is equipped with an adhesive coating based on polyacrylate.
NOBADERM® as primary wound dressing protects wounds from the penetration of germs and serves as catheter fixation.

Composition

Polyurethane film, adhesive based on polyacrylate

Contraindications

Do not use NOBADERM® for infected wounds. Not suited as primary wound dressing for heavily bleeding or highly exuding wounds. Do not use if there is a known allergy to one of the ingredients of NOBADERM®.

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 product does not contain dangerous toxic substances according to REACH.
Sterilization of the product complies with DIN EN ISO 11135.

Packaging

Primary packaging:	paper-paper packaging
Secondary packaging:	folding box made of cellulose
Tertiary 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

Expiry date on all packaging levels, protect against moisture, sunlight and heat, store in a dust-free environment at room temperature. The product must no longer be used after the expiry date has passed.

Sterile device

Contents sterile only if package is intact. If the primary package is damaged, the product may no longer be used.

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

Used material is disposed of in accordance with the requirements of statutory regulations. This is the responsibility of the respective institution.