



**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](http://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.