

# NOBAMED Paul Danz AG

# **NOBADERM®**

### **REF 161015**

# Product Description, Intended use, **Application**

NOBADERM® (10 cm x 15 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 and 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-film

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

According locally applicable to legal regulations and standards of infection prophylaxis.

Product Data Sheet: 23.08.2023 [REV 0]