

NOBAMED Paul Danz AG

NOBALUMENAL®

REF 873550

Product Description, Intended use, Application

The eye pad, **size 54 x 70 mm** consists of a soft non-woven and is provided with an absorbent filling. It is closed all around so that no fluffs can emerge. Due to its **oval shape** the pad adapts to the eye socket. The eye pad supports eye dressing as absorbend, padding, protecting or caring part. NOBALUMENAL[®] is for single use only and must be sterilized with a validated procedure (radiation in accordance with DIN EN ISO 11137, or ethylene oxide in accordance with DIN EN ISO 11135).

Composition

Polyester, viscose, 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.

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

Packaging

Primary packaging:

Secondary packaging:

folding box made of cellulose

carton made of cellulose

Symbols used in labelling

Explanations at <u>www.nobamed.com</u>



Sterilize before use on open wounds.

Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN 1041.

Storage and Transport

Dry and dustfree, protect from sunlight.

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.