



NOBAMED Paul Danz AG

NOBA[®] HEMD

REF 324043

Product Description, Intended use, Application

The disposable product NOBA[®] HEMD, **for children, large (size 122-158)**, is a finely woven, very tightly knitted shirt, natural-coloured, with a ribbed structure. Its high elasticity guarantees best adaptability. The unbleached cotton is water-repellent. Due to its natural fibre, the material has hypoallergenic features and is very skin-tolerant. The shirt is used under rigid or half-rigid cast bandages. In the case of dermatological diseases, the NOBA[®] HEMD serves as cover for ointment dressings or similar forms of therapy.

Composition

Cotton

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 the MDD 93/42/EEC and MDR (EU) 2017/745.

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

Packaging

| | | |
|----------------------|---------------------------|--------|
| Primary packaging: | Folding made of cellulose | box of |
| Secondary 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 ISO 20417.

Storage and Transport

To be stored in a dry and dust-free environment

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.