

NOBAMED Paul Danz AG

NOBA® HEMD

REF 324044

Product Description, Intended use, Application

The disposable product NOBA® HEMD, for adults, small (for women up to size 44 or men up to size 50), 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 box

made of

cellulose

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.

Product Data Sheet: August 17, 2021 [REV 6] replaced: April 01, 2020 [Rev 5]