



NOBAMED Paul Danz AG

NOBA[®] FÄUSTLING

REF 324747

Product Description, Intended use, Application

Finely woven, natural coloured, densely knitted, thumbless mitten, size large (infants) which is made of 100% unbleached cotton. The unbleached cotton has a water repellent character. Due to the natural fibre, the material has hypoallergenic features with high skin tolerance. For the fixation at the wrist a finely knitted band is sewn-on. The disposable product NOBA[®] FÄUSTLING serves for self-protection of the newborn baby or the infant in case of strong itching of the body. The mitten prevents the child from causing additional skin damage by scratching. In case of dermatological diseases on the hands, the mitten serves as a cover for ointment dressings or other forms of therapy.

Composition

Cotton

Notes

The product has been subjected to a validated microbial reduction process and is therefore pre-sterilized.

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 Regulatory 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:
Secondary Packaging

OPP-bag
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 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.