



NOBAMED Paul Danz AG

NOBASTEP®

REF 944599

Product Description, Intended use, application

NOBASTEP® walking cast shoe (size XXS, shoe size 25-30) is used with a thigh bandage or lower leg bandage (made of cast or of synthetic material). Due to its three hook-and-loop fasteners, it can safely be fixed to the cast bandage. NOBASTEP® may be used on the left or on the right. The material is water and dirt resistant. NOBASTEP® is washable at 30°C.

Composition

PVC, TPR (thermoplastic styrene, butadiene plastic), polystyrole, naphthenic oil, calcium carbonate, zinc stearate, black dye), cardboard, EVA (ethylene vinyl acetate), polyester and nylon

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

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

No special conditions

Single use device

Intended for use on one patient. The reprocessing of single use devices for reuse can decrease the product's performance significantly. Reusing a single use device can lead to microbiological danger.

Disposal

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