

## NOBAMED Paul Danz AG

### **NOBASTEP®**

### **REF 944599**

## Product Description, Intended use, application

The medical 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). It enables walking with a support bandage and allows secure fixation thanks to the three Velcro fasteners 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 <u>www.nobamed.com</u>





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.