



NOBAMED Paul Danz AG

SLIPPER

REF 944042

Product Description, Intended use, Application

Disposable shoe, size 42, in slip-on form for patients. It is packed in pairs and consists of blue non-woven and a sole made of EVAC. The product is worn in medical facilities such as hospitals and day clinics and prevents the spread of contamination.

Composition

Polypropylene, EVAC (ethylene-vinyl acetate-copolymer)

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

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

Packaging

Primary:	PE pouch
Secondary:	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

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.