



NOBAMED Paul Danz AG

NOBASHUCO®

REF 675100

Product Description, Intended use, Application

The shoe covers made of foil are worn over the shoes when entering the intensive or clean room area for a short time.

Composition

CPE

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

Primary: PE bag

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

Dry and dustfree

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.