

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

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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 <u>www.nobamed.com</u>



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1and 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.