



NOBAMED Paul Danz AG

NOBASUIT®-Hose

REF 662130 (as of LOT)

Product Description, Intended use, Application

The disposable NOBASUIT® trousers in green, **size XXXL**, serve as scrub clothing and clean air clothing to reduce the spreading of infectious agents. The material is antistatic, breathable, low-particle, convenient and comfortable to wear. Trousers with straight cut, one back pocket and drawstring waist. The product is for single use only.

Composition

Polypropylene (SMS)

Contraindication

The product should not be used in the case of a known allergy against the material.

Note

The product has been subjected to a validated microbial reduction process and is therefore pre-sterilized

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 MDR (EU) 2017/745.

The product complies with the requirements of DIN EN 13795-2 for clean air suits.

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

Packaging

Primary packaging: PE-bag

Secondary 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

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.