

# NOBAMED Paul Danz AG

# **NOBASUIT®-Hose**

## REF 662100 (as of LOT 135288)

## Product Description, Intended use, **Application**

The disposable NOBASUIT® trousers in green, size S, 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.

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.

Product Data Sheet: February 27, 2023 [REV 5], replaces: October 26, 2021 [REV 4]