



**NOBAMED Paul Danz AG**

## NOBASUIT<sup>®</sup>-Kasack

REF 663120 (as of LOT 135288)

### Product Description, Intended use, Application

The disposable NOBASUIT<sup>®</sup> tunic in green, size **XXL**, 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. Tunic with V-neck and 2 pockets, one in chest area. 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](http://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.