



NOBAMED Paul Danz AG

NOBASUIT®-Kasack

REF 663130 (as of LOT 136888)

Product Description, Intended use, Application

The disposable NOBASUIT® tunic 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. 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 Regulatory 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.