



NOBAMED Paul Danz AG

NOBA[®]-Endoskopiehose

REF 676100

Product description, intended use, application

The endoscopy pants (size XXXL) are used to maintain the patients' private sphere during endoscopic examinations, to protect them from the cold at the same time and to avoid contaminations. The pants have an opening at the back that can be closed with a hook and loop fastener.

Composition

Polypropylene, elastomer

Contraindications

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

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 *MDD 93/42/EEC, MDR (EU) 2017/745*.

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

Packaging

Primary packaging: plastic bag

Secondary packaging: carton made of cellulose

Symbols used in labelling

Explanation 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 dust free, protect from sunlight.

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.