



NOBAMED Paul Danz AG

NOBADRESS®-Perfect

without reinforcement

REF 623160

Product Description, Intended use, Application

NOBADRESS®-Perfect (size XXL) is a disposable surgical gown in compliance EN 13795-1 with good wearing properties. It is used to prevent the transfer of infective agents. The blue surgical gown is individually sterile packed and consists of a low-particle SSMMS non-woven fabric. Due to its material composition, the gown has breathable properties and simultaneously protects from fluid and germs. The surgical gown has got knitted cuffs at its sleeves. Two sterile towels are packed with each gown.

Composition

Polypropylene, polyester

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 Legal Requirements

Medical Device according to *MDD 93/42/EEC, MDR (EU) 2017/745*.

NOBADRESS®-Perfect complies with the requirements of the **EN 13795-1**, "Surgical clothing and drapes – Requirements and test methods – Part 1: Surgical drapes and gowns (requirements of the performance level 'standard')".

Sterilization of the product complies with DIN EN 11135.

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

Packaging

Primary packaging: paper-film packaging

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 dustfree, protect from sunlight.

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

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.