



NOBAMED Paul Danz AG

NOBADRESS®-Comfort

without reinforcement

REF 621150 (as of LOT 136857)

Product Description, Intended use, Application

NOBADRESS®-Comfort (size XL) is a blue disposable surgical gown made of a low-particle spunlace non-woven fabric. Due to its material composition, it has breathable properties that ensure a high level of wearing comfort, especially during longer periods of wear. The surgical gown has knitted cuffs at its sleeves. Two sterile towels are packed with each gown. The product is individually sterile packed. NOBADRESS®-Comfort prevents the transmission of infective agents.

Composition

Cellulose, polyester

Contraindications

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

Normative and Regulatory Requirements, Common Standards

Medical Device according to MDR (EU) 2017/745.

The product complies with the requirements of the **DIN 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: paper-film packaging

Secondary: carton made of cellulose

Symbols used in labelling

Explanation at www.nobamed.com



CE
0123

Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN ISO 20417

Storage and transport

To be stored in a dry and dust-free environment

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.