



**NOBAMED Paul Danz AG**

# **NOBADRESS®-Perfect**

**without reinforcement**

**REF 623130**

## **Product Description, Intended use, Application**

NOBADRESS®-Perfect (size L) 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](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, 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.