NOBASET®

BESUCHERKITTEL-steril
(Visitor gown-sterile)

REF 665051 (as of LOT 35944)

Contents of this procedure pack:

1 x visitor gown blue, universal size
NOBAMED Paul Danz AG, MD CE

1 x NOBAWRAP®, 60 x 60 cm, NOBAMED Paul Danz AG MD CE

Product Description, Intended use, Application
The sterile procedure pack consists of a visitor gown and NOBAWRAP®.
The visitor's gown is made of spunbonded nonwoven. The gown is open in the back. It has long sleeves and an elastic band at the wrist, with ties at waist and collar. Due to the breathable material, the product is comfortable to wear. The colour of the gown can be used for the assignment to specific sectors and for the identification "visitors". The use of the gown reduces the spread of germs through contaminated street clothes from the visitor to the patient. The inner packaging of the sterile procedure pack also serves as an underlay and possibility to lay down the gown, which makes it easier for visitors to put on the gown.

Composition
Visitor gown: polypropylene, sleeve cuff: polyester
NOBAWRAP®: Cellulose, polyethylene

This product is for single and temporary use on one patient and must be applied by specially trained medical personnel. Any information for use that is available for individual products must be observed!

Normative and Legal Requirements
Procedure Pack according to Art. 22, Medical Device Regulation (EU) 2017/745,
risk class I.

The compatibility of the customized medical devices or other products has been assessed with due regard for the indications of the respective manufacturers, and operations have been performed in accordance with the aforementioned indications.

The manufacturers' intended use is not changed.

The systems and procedure packs are packed in compliance with a validated procedure.

All activity is properly monitored and controlled as part of our QM system, in accordance with DIN EN ISO 13485:2016.

A validated sterilization process is used for sterile procedure packs, taking into account the manufacturers' instructions, so that product functionality and product safety of the components are maintained after a system or procedure pack has been compiled and sterilized.

Sterilization and packaging are subject to supervision of our Notified Body TÜV Süd PS 0123 pursuant to Annex XI, Part A.

The product does not contain dangerous toxic substances according to REACH. It has CE marking and DIN EN ISO 15223-1 labels on all its packaging

Storage
To be stored in a dry and dust-free environment, protect from sunlight.

The product bears following labels and symbols