NOBASET®

NOBANATAL®

REF 678010 (as of LOT 36156)

Contents of this procedure pack:

2 x NOBATOP® 12 7,5 x 7,5 cm, NOBAMED Paul Danz AG, MD CE

2 x NOBATOP® S 7,5 x 7,5 cm, 6-fach, NOBAMED Paul Danz AG, MD CE

1 x Nabelklemme (umbilical clamp), NOBAMED Paul Danz AG, MD CE

1 x Nabelbinde (umbilical bandage) 6 cm, NOBAMED Paul Danz AG, MD CE

Product description, Intended use, Application
The sterile procedure pack with umbilical clamp, non-woven swabs with and without slit and umbilical bandage is used for the initial care of the umbilical stump of new-borns. The clamp for the umbilical cord has a locking mechanism that causes that the clamp cannot be opened after closing, which becomes clear by a click noise. The swabs are made of a soft non-woven and are therefore gentle to the skin. The lengthwise elastic umbilical bandage (width: 6 cm, stretched length: 2 m) is used to cover the umbilical stump located between the swabs.

Composition:
NOBATOP® and umbilical bandage: Viscose, polyester, umbilical clamp: 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.

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

The product bears following labels and symbols