



NABELKLEMME-steril

REF 679101

Contents of this procedure pack:

1 x Umbilical clip,
NOBAMED Paul Danz AG, CE

1 x NOBATOP®8 5x5cm,
NOBAMED Paul Danz AG, CE

Product Description, Intended use, Application

The sterile procedure pack consists of a white umbilical clip and one NOBATOP® non-woven swab and is used for the care of the umbilical stump of newborn babies. The clamp for disconnecting the umbilical cord after birth, has a locking mechanism that causes that the clamp can not be opened after closing, which becomes clear by a click noise.

Composition

Clamp: polyethylene
Swab: viscose, polyester



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. 12 of the Medical Device Directive 93/42 / EEC

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.

If a sterilization is intended, a validated sterilization procedure will be used, 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 V.

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.

The product bears following labels and symbols

