

REF 731810 (as of LOT 37080)

Contents of this procedure pack:

1 x NOBALAN[®] 10 cm x 5 m, MD C€

1 x NOBAWRAP[®], MDCE

Product Description, Intended use, Application

The sterile procedure pack consists of one textile elastic, short stretch bandage NOBA-LAN[®] and one NOBAWRAP wrapping cloth, which enables safe removal, serves as a table underlay and prevents the bandage from unravelling. Due to its stretchability of approx. 85%, NOBALAN[®] can be used for the application of a compression bandage for the treatment of phlebological or lymphological diseases of the legs or arms.

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.

CE and DIN EN ISO 15223-1 markings of the components can be found on all packaging levels.

Storage and Transport

Dry and dustfree, protect from sunlight.

Symbols used in labelling

Explanation at www.nobamed.com

