

We,

**BSN medical GmbH
Schützenstr. 1-3
22761 Hamburg
Germany
(SRN: DE-MF-000005787)**

hereby declare under our sole responsibility, that this product family complies with the applicable requirements of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product Name:

Elastofix® / Leukoplast® elastofix®

Basic UDI-DI:

404280940036778A9

Intended purpose:

Elastofix® / Leukoplast® elastofix® is intended to provide light support or compression, fixation or protection in post-traumatic and post-operative usage. Application fields include:
- Light support in the treatment of minor soft tissue and joint injuries
- Light compression to reduce effusion and swelling
- Secure dressings, e.g. when treating wounds
- Protect the skin from e.g. cast material, when used as an undercast bandage
The products are applied on intact skin only. Wounds have to be treated before by using an appropriate wound dressing.

Conformity assessment route: **Annex II+III**

Classification rule:

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Classification:

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The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

Declaration of conformity issued: 13.11.2024

Compiled and released:

Hamburg, 13.11.2024
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
02140-00000-04	ELASTOFIX 25M SIZE A WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	02140-00
02141-00000-04	ELASTOFIX 25M SIZE B WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	02141-00
02142-00000-04	ELASTOFIX 25M SIZE C WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	02142-00
02143-00000-04	ELASTOFIX 25M SIZE D WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV	02143-00
71211-00000-01	LEUKOPLAST ELASTOFIX STRETCH 2.5M WHITE 1 IT PT ES TRUNK	71211-00
71211-00001-01	LEUKOPLAST ELASTOFIX STRETCH 2.5M WHITE 1 IT PT ES HEAD	71211-01
71211-00002-01	LEUKOPLAST ELASTOFIX STRETCH 2.5M WHITE 1 IT PT ES KNEE	71211-02
71211-00003-01	LEUKOPLAST ELASTOFIX STRETCH 2.5M WHITE 1 IT PT ES FOOT	71211-03
71211-00004-01	LEUKOPLAST ELASTOFIX STRETCH 2.5M WHITE 1 IT PT ES HAND	71211-04
71211-00005-01	LEUKOPLAST ELASTOFIX STRETCH 2.5M WHITE 1 IT PT ES FINGER	71211-05
71211-00006-01	LEUKOPLAST ELASTOFIX STRETCH 2.5M WHITE 1 IT PT ES UMBILICUS	71211-06