

We,

**BSN medical (Pty) Ltd
30 Gillits Road;
3610 Pinetown
South Africa
(SRN: ZA-MF-000022653)**

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:

Tensoplast®

Basic UDI-DI:

40428094003529497

Intended purpose:

Tensoplast® Elastic adhesive bandages are intended for compressive strapping/taping and dressing fixation purposes. Application fields include:

- **Soft tissue injuries (e.g. strains, sprains)**
- **Injury prevention (e.g. stabilization of joints)**
- **Late-phase stabilization in fracture management (e.g. after cast removal)**
- **Posture improvement**
- **Elasto-compressive treatment in phlebology**

Conformity assessment route:

Annex II+III

Classification rule:

1

Classification:

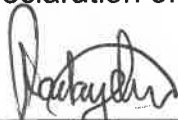
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The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

European Authorized Representative:

**BSN medical GmbH
Schützenstr. 1-3
22761 Hamburg
Germany
(SRN: DE-AR-000005791)**

Declaration of conformity issued: 06.08.2024



Compiled and released:

Pinetown, 06.08.2024
Lawrence PADAYACHEE
Regulatory Affairs Specialist
BSN medical (Pty) Ltd

Article	Description	REF
71545-00000-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 5CM X 4.5M CREAM 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (1 ROLL/BOX)	71545-00
71545-00004-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 5CMX4.5M 1 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR RECODE 71545-00-02	71545-04
71545-00005-00	TENSOPLAST ELASTIC ADHESIVE BANDAGE 5CM X 2.7M CREAM 1 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV MX	71545-05
71545-00006-00	TENSOPLAST ELASTIC ADHESIVE BANDAGE 7.5CM X 2.7M CREAM 1 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV MX	71545-06
71545-00007-00	TENSOPLAST ELASTIC ADHESIVE BANDAGE 10CM X 2.7M CREAM 1 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV MX	71545-07
71546-00000-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 7.5CMX4.5M CREAM 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (1 ROLL/BOX)	71546-00
71546-00014-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 7.5CMX4.5M 1 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR RECODE71546-00-02	71546-14
71547-00000-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 10CMX4.5M CREAM 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (1 ROLL/BOX)	71547-00
71547-00005-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 10CMX4.5M 1 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR RECODE 71547-0-02	71547-05
72050-00029-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 10CM X 4.5M CREAM 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR	72050-29
72050-00032-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 5CM X 4.5M CREAM 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR	72050-32
72050-00034-02	TENSOPLAST 7.5CM X 4.5M 48 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (6/POLYBAG)	72050-34
72050-00036-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 7.5CM X 4.5M CREAM 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR	72050-36

Article	Description	REF
72050-00049-02	TENSOPLAST 10CM X 2.5M CREAM 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR	72050-49
72050-00052-02	TENSOPLAST 5CM X 2.5M CREAM 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR	72050-52
72050-00053-02	TENSOPLAST 7.5CM X 2.5M CREAM 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR	72050-53
72050-00059-02	TENSOPLAST 5CM X 4.5M CREAM 60 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR VET PACK (6/POLYBAG)	72050-59
73054-00000-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 5CMX4.5M CREAM 1 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (71545-0-2RECODED)	73054-00
73054-00001-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 7.5CMX4.5M CREAM 1 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (71546-0-2 RECODED)	73054-01
73054-00002-02	TENSOPLAST ELASTIC ADHESIVE BANDAGE 10CMX4.5M CREAM 1 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (71547-0-2 RECODED)	73054-02