

We,

**BSN medical (Pty) Ltd
30 Gillits Road;
3610 Pinetown
South Africa
(SRN: NOT ISSUED YET)**

hereby declare under our own responsibility, that this product family complies with the applicable regulations 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: **I**

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:

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Gona Govender

BSN medical (Pty) Ltd

Article	Description	REF
71545-00000-01	TENSOPLAST ELASTIC ADHESIVE BANDAGE 5CM X 4.5M 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (1 ROLL/BOX)	71545-00
71546-00000-01	TENSOPLAST ELASTIC ADHESIVE BANDAGE 7.5CM X 4.5M 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (1 ROLL/BOX)	71546-00
71547-00000-01	TENSOPLAST ELASTIC ADHESIVE BANDAGE 10CM X 4.5M 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (1 ROLL/BOX)	71547-00
72050-00029-01	TENSOPLAST 10CM X 4.5M 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR	72050-29
72050-00032-01	TENSOPLAST 5CM X 4.5M 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR	72050-32
72050-00034-01	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
72050-00036-01	TENSOPLAST 7.5CM X 4.5M 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR	72050-36
72050-00049-01	TENSOPLAST 10CM X 2.5M 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR ROLL	72050-49
72050-00052-01	TENSOPLAST 5CM X 2.5M 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR ROLL	72050-52
72050-00053-01	TENSOPLAST 7.5CM X 2.5M 12 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR ROLL	72050-53
72050-00059-01	TENSOPLAST 5CM X 4.5M CREAM 60 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR VET PACK	72050-59
73054-00000-01	TENSOPLAST ELASTIC ADHESIVE BANDAGE 5CMX4.5M 1 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (71545-0-1 RECODED)	73054-00
73054-00001-01	TENSOPLAST ELASTIC ADHESIVE BANDAGE 7.5CMX4.5M 1 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (71546-0-1 RECODED)	73054-01
73054-00002-01	TENSOPLAST ELASTIC ADHESIVE BANDAGE 10CMX4.5M 1 EN DE FR ES PT IT NL SV NO DA FI GR ZH JA AR (71547-0-1 RECODED)	73054-02