

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 STK**

Basic UDI-DI:

**4042809400356759P**

Intended purpose:

**Tensoplast® Skin Traction Kits - Adhesive are intended for:**

- **Weight traction:** For simple weight traction, using a single weight pulley, one cord should be cut off short 20 cm from the spreader and tied firmly around the other cord.
- **Thomas Splint:** No modification is required. In order to encourage medical rotation, it is important to pass the cords round the side bars of the splint and tie them across the end of the splint.
- **Russell traction:** For Russell traction cut off cords 20 cm from the spreader and tie through a small loose pulley block.
- **Disc lesions:** Disc lesions can be treated by applying simple weight traction to one or both legs with a light weight (1 kg) being used. The cords are positioned over the end of the bed instead of a pulley.

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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Compiled and released:

Pinetown, 05.06.2023  
Julie Maharaj

BSN medical (Pty) Ltd

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Date of Issue: 05.06.2023

Article	Description	REF
71544-00000-03	TENSOPLAST SKIN TRACTION KITS ADHESIVE ADULT 12 EN DE FR ES PT IT NL SV NO DA FI CZ GR ZH AR	71544-00
71544-00004-03	TENSOPLAST SKIN TRACTION KITS ADHESIVE ADULT WHITE 1 REPACK 71544-00-03	71544-04
71554-00000-03	TENSOPLAST SKIN TRACTION KITS ADHESIVE CHILD 12 EN DE FR ES PT IT NL SV NO DA FI CZ GR ZH AR	71554-00
71554-00003-03	TENSOPLAST SKIN TRACTION KITS ADHESIVE CHILD WHITE 1 EN DE FR ES PT IT NL SV NO DA FI CZ GR ZH AR REPACK 71554-00-3	71554-03
71554-00004-03	TENSOPLAST SKIN TRACTION KITS ADHESIVE INFANT WHITE 1 EN DE FR ES PT IT NL SV NO DA FI CZ GR ZH AR 71554-10-3 REPACK	71554-04
71554-00010-03	TENSOPLAST SKIN TRACTION KITS ADHESIVE INFANT 12 EN DE FR ES PT IT NL SV NO DA FI CZ GR ZH AR	71554-10