

**BSN medical (Pty) Ltd** 30 Gillitts Road, Pinetown, 3610 P.O. Box 526, Pinetown, 3600 Republic of South Africa Tel : +27-31 710 8111 Fax : +27-31 710 8108

## PRODUCT FAMILY: TENSOPLAST ELASTIC ADHESIVE BANDAGE

We, BSN medical (Pty) Ltd.

hereby declare under our own responsibility, that the above mentioned product family

CE-class 1

containing the products:

71545-00000-00- TENSOPLAST EAB 5cm x 4.5m(Str) 71546-00000-00- TENSOPLAST EAB 7.5cm x 4.5m(Str) 71547-00000-00 - TENSOPLAST EAB 10cm x 4.5m(Str) 72050-00122-00- TENSOPLAST EAB 5cm x 4.5m(Str) 72050-00123-00- TENSOPLAST EAB 7.5cm x 4.5m(Str) 72050-00124-00- TENSOPLAST EAB 10cm x 4.5m(Str)

complies with the applicable regulations of the MDD93/42/EEC of 14 June 1993 and that the products fulfil the essentials requirements as defined in Annex 1.

Technical dossier reference: SA13.

This Declaration of Conformity is performed in compliance with the Quality Management System according to ISO 13485.

Product is designed , manufactured and tested in accordance with the information in part B of the above referenced dossier.

Signed:

Date:

MJ Weehuizen Technical Manager

02/07/2014.

Company Registration No. 2001/003941/07

Directors : N R von Klemperer, D , Lavender