BSN medical
an Essity company

30 **BSN medical (Pty) Ltd**
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Republic of South Africa
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essity

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:

72050-00122-00 - TENSOPLAST EAB 5cm x 4.5m(Stretched)
72050-00123-00 - TENSOPLAST EAB 7.5cm x 4.5m(Stretched)
72050-00124-00 - TENSOPLAST EAB 10cm x 4.5m(Stretched)
72050-00031-00 - TENSOPLAST EAB 5cm x 4.5m(Stretched)
72050-00035-00 - TENSOPLAST EAB 7.5cm x 4.5m(Stretched)
72050-00028-00 - TENSOPLAST EAB 10cm x 4.5m(Stretched)
72050-00032-00 - TENSOPLAST EAB 5cm x 4.5m(Stretched)
72050-00036-00 -TENSOPLAST EAB 7.5cm x 4.5m(Stretched)
72050-00029-00 - TENSOPLAST EAB 10cm x 4.5m(Stretched)
72050-00052-00 - TENSOPLAST EAB 5cm x 4.5m(Stretched)
72050-00053-00 - TENSOPLAST EAB 7.5cm x 4.5m(Stretched)
72050-00049-00 - TENSOPLAST EAB 10cm x 4.5m(Stretched)
71545-00000-00 - TENSOPLAST EAB 5cm x 4.5m(Stretched)
71546-00000-00 -TENSOPLAST EAB 7.5cm x 4.5m(Stretched)
71547-00000-00 - TENSOPLAST EAB 10cm x 4.5m(Stretched)
71547-00004-01 - TENSOPLAST EAB 5cm x 4.5m(Stretched)
71545-00003-01 - TENSOPLAST EAB 7.5cm x 4.5m(Stretched)
71547-00001-01 - TENSOPLAST EAB 10cm x 4.5m(Stretched)
71546-00005-00 - TENSOPLAST EAB 5cm x 4.5m(Stretched)
71546-00006-00 - TENSOPLAST EAB 7.5cm x 4.5m(Stretched)
71546-00004-00 - TENSOPLAST EAB 10cm x 4.5m(Stretched)

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.

Legal Manufacturer
BSN medical (Pty)Ltd
30 Gillitts Road ,Pinetown,3610
P.O Box 526 Pinetown,3610
Republic of South Africa

EU Representative
BSN medical GmbH
Quickbornstrasse 24
Hamburg , Germany 20253

Technical dossier reference: SA01.

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:

Gona Govender
QA/RA Manager

Date: 22/05/2019