

We,

**BSN medical Inc.
5825 Carnegie Blvd.
28209 Charlotte,
USA
(SRN: US-MF-000019174)**

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:

TRICOFIX

Basic UDI-DI:

4042809400401167N

Intended purpose:

Tricofix® is intended to provide light support or compression, fixation or protection. Application fields include:
-#Light support in the treatment of minor soft tissue and joint injuries
-#Light compression to reduce effusion and swelling
-#Secure dressings, e.g. when treating wounds
-#Protect the skin from e.g. cast material, when used as an undercast bandage

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:

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

Date of Issue: 02.05.2023

Andreas Matthies

Digitally signed by dehanta
DN: dc=net, dc=ecdomain, ou=EU, ou=DE, ou=HAM, ou=C3113016,
ou=Users, cn=dehanta, email=andreas.matthies@essity.com
Date: 2023.05.02 19:48:57 +02'00'

Compiled and released:

Charlotte,, 02.05.2023
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
02191-00000-08	TRICOFIX A/1 1.7CM X 20M WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	02191-00
02192-00000-08	TRICOFIX B/2 20M X 2.7CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	02192-00
02193-00000-08	TRICOFIX C/3 20M X 4.3CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	02193-00
02195-00000-08	TRICOFIX D/5 20M X 6.2CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	02195-00
02195-00001-08	TRICOFIX TUBULAR BANDAGE 6CM X 20M WHITE 1 EN FR D/5	02195-01
02197-00000-08	TRICOFIX E/6 20M X 8.2CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	02197-00
02197-00001-08	TRICOFIX TUBULAR BANDAGE 8CM X 20M E6 WHITE 1 EN FR	02197-01
02198-00000-08	TRICOFIX F/7 20M X 10.2CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	02198-00
02198-00001-08	TRICOFIX TUBULAR BANDAGE 10CM X 20M WHITE 1 EN FR F/7	02198-01
02199-00000-08	TRICOFIX G/9 20M X 11.7CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	02199-00
02199-00001-08	TRICOFIX TUBULAR BANDAGE BANDAGE 12CM X 20M WHITE 1 EN FR	02199-01
02201-00000-08	TRICOFIX K 15.5CM X 10M WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	02201-00
02202-00000-08	TRICOFIX L 10M X 23.5CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV	02202-00