

We,

**BSN medical Inc.  
5825 Carnegie Blvd.  
28209 Charlotte,  
USA  
(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: **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  
Quickbornstrasse 24  
20253 Hamburg  
Germany  
(SRN: NOT ISSUED YET)**

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Compiled and released:

Charlotte,, 06/01/2020  
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Director Regulatory Affairs, LM NA  
BSN medical Inc.

| Article        | Description                                                        | REF      |
|----------------|--------------------------------------------------------------------|----------|
| 02184-00000-06 | TRICOFIX WHITE 50 DA NL EN FI FR DE IT NO PT ES SV FINGER          | 02184-00 |
| 02191-00000-06 | TRICOFIX A/1 1.7CM X 20M WHITE 1 DA NL EN FI FR DE IT NO PT ES SV  | 02191-00 |
| 02192-00000-06 | TRICOFIX B/2 20M X 2.7CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV  | 02192-00 |
| 02193-00000-06 | TRICOFIX C/3 20M X 4.3CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV  | 02193-00 |
| 02195-00000-07 | TRICOFIX D/5 20M X 6.2CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV  | 02195-00 |
| 02195-00001-02 | TRICOFIX TUBULAR BANDAGE 6CM X 20M WHITE 1 EN FR D/5               | 02195-01 |
| 02197-00000-07 | TRICOFIX E/6 20M X 8.2CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV  | 02197-00 |
| 02197-00001-02 | TRICOFIX TUBULAR BANDAGE 8CM X 20M WHITE 1 EN FR E/6               | 02197-01 |
| 02198-00000-07 | TRICOFIX F/7 20M X 10.2CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV | 02198-00 |
| 02198-00001-02 | TRICOFIX TUBULAR BANDAGE 10CM X 20M WHITE 1 EN FR F/7              | 02198-01 |
| 02199-00000-06 | TRICOFIX G/9 20M X 11.7CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV | 02199-00 |
| 02199-00001-02 | TRICOFIX TUBULAR BANDAGE BANDAGE 12CM X 20M WHITE 1 EN FR          | 02199-01 |
| 02201-00000-06 | TRICOFIX K 15.5CM X 10M WHITE 1 DA NL EN FI FR DE IT NO PT ES SV   | 02201-00 |
| 02202-00000-06 | TRICOFIX L 10M X 23.5CM WHITE 1 DA NL EN FI FR DE IT NO PT ES SV   | 02202-00 |