

We,

**BSN medical GmbH  
Schützenstr. 1-3  
22761 Hamburg  
Germany  
(SRN: DE-MF-000005787)**

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:

**Tensofast® double stretch**

Basic UDI-DI:

**4042809400375069D**

Intended purpose:

**Tensofast® Double Stretch is intended to provide light support or compression, fixation or protection in post-traumatic and post-operative usage. 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**  
**The products are applied on intact skin only. Wounds have to be treated before by using an appropriate wound dressing.**

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.

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Hamburg, 30.06.2023  
Dr. Thomas Mehler  
Global Quality Director Medical  
BSN medical GmbH



| Article        | Description                                                                         | REF      |
|----------------|-------------------------------------------------------------------------------------|----------|
| 73447-00000-03 | TENSOFAST DOUBLE STRETCH 3.5CMX10M<br>WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV   | 73447-00 |
| 73447-00001-03 | TENSOFAST DOUBLE STRETCH 5CMX10M<br>WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV     | 73447-01 |
| 73447-00002-03 | TENSOFAST DOUBLE STRETCH 7.5CMX10M<br>WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV   | 73447-02 |
| 73447-00003-03 | TENSOFAST DOUBLE STRETCH 10.75CMX10M<br>WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV | 73447-03 |
| 73447-00004-03 | TENSOFAST DOUBLE STRETCH 17.5CMX10M<br>WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV  | 73447-04 |
| 73447-00012-03 | TENSOFAST DOUBLE STRETCH 7.5CMX1M<br>WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV    | 73447-12 |