

We,

**BSN Medical SAS
1 rue du Millenaire
72320 VIBRAYE
France
(SRN: FR-MF-000000598)**

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:

Tensoplast® Sport

Basic UDI-DI:

4042809400365569M

Intended purpose:

Tensoplast Sport is intended for compressive strapping/taping and dressing fixation purposes.

Application fields include:

- **Soft tissue injuries (e.g. strains, sprains)**
- **Injury prevention (e.g. stabilization of joints)**
- **Late-phase stabilization in fracture management (e.g. after cast removal)**
- **Posture improvement**
- **Elasto-compressive treatment in phlebology**

The device is non-sterile and for single application use only. Intended duration of usage for not more than 30 days. Intended users are Health Care Professionals and Patients. The use of the product is not restricted to a specific population.

Conformity assessment route: **Annex II+III**

Classification rule:

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Classification:

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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.

Declaration of conformity issued: 23.09.2024

Compiled and released:


VIBRAYE, 23.09.2024
Philippe Hatet
Senior Project Manager
BSN Medical SAS

Article	Description	REF
71548-00000-03	TENSOPLAST SPORT 3CM X 2.5M 1 EN	71548-00
71549-00000-03	TENSOPLAST SPORT 6CM X 2.5M WHITE 1 EN	71549-00
71550-00000-03	TENSOPLAST SPORT 8CM X 2.5M WHITE 1 EN	71550-00
71551-00000-03	TENSOPLAST SPORT 10CM X 2.5M WHITE 1 EN	71551-00
71552-00000-03	TENSOPLAST SPORT 15CM X 2.5M WHITE 1 EN HB	71552-00