

We,

**BSN Medical SAS
Rue du Millenaire / CS 90022
72320 VIBRAYE
France
(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: **Tensoplast®**
Basic UDI-DI: **4042809400362028F**

Intended purpose: **Tensoplast HB 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: **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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Site Manager Vibraye
BSN Medical SAS

Article	Description	REF
72050-00066-01	TENSOPLAST 3CM X 2.5M 1 FR HB HO	72050-66
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72050-00073-01	TENSOPLAST 20CM X 2.5M 1 FR HB PH	72050-73
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72050-00084-01	TENSOPLAST 10CM X 2.5M 1 FR HB AV CONS	72050-84
72050-00085-01	TENSOPLAST 3CM X 2.5M 1 FR HB SV CONS	72050-85
72050-00086-01	TENSOPLAST 6CM X 2.5M 1 FR HB SV CONS	72050-86
72050-00087-01	TENSOPLAST 8CM X 2.5M 1 FR HB SV CONS	72050-87
72050-00088-01	TENSOPLAST 10CM X 2.5M 1 FR HB SV CONS	72050-88