We,

BSN Medical SAS
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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:	**Tensoban®**
Basic UDI-DI:	**4042809400363018J**
Intended purpose:	**Tensoban is intended for:** **- Skin protection under adhesive bandages (especially during sport activities, or the treatment of venous insufficiency of the lower limbs)** **- Reduction of skin irritations while bandages removal** **The device is non-sterile and for single application use only. Intended Users are Health Care Professionals and Patients. Use of product is not restricted to specific populations.**
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.

Declaration of conformity issued: 22.11.2024

Compiled and released:

VIBRAYE, 22.11.2024
Philippe Hatet
Senior Project Manager
BSN Medical SAS

Article	Description	REF
71500-00001-03	TENSOBAN 10CM X 20M WHITE 10 NL EN FR DE IT	71500-01
71500-00005-03	TENSOBAN 7CM X 20M WHITE 1 FR EN DE ES IT NL	71500-05
71500-00006-03	TENSOBAN 10CM X 20M WHITE 1 FR EN DE ES IT NL	71500-06
71500-00007-03	TENSOBAN 7CM X 20M WHITE 1 FR EN DE ES IT NL 12/BOX	71500-07
71500-00008-03	TENSOBAN BANDAGE 7CM X 20M WHITE 12 CS DA NL EN FI FR DE IT NO PT ES SV UNDERWRAP	71500-08