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:	**Tensoplus®**
Basic UDI-DI:	**4042809400364789S**
Intended purpose:	**Tensoplus is intended for fixation of wound dressings of all types and sizes as well as devices such as splints, tubes and paddings, for short term application of compression and to provide general support. The device is non-sterile and reusable. 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: 08.11.2024

Compiled and released:

VIBRAYE, 08.11.2024
Philippe Hatet
Senior Project Manager
BSN Medical SAS

Article	Description	REF
72097-00006-04	TENSOPLUS COHESIVE 8CM X 3M WHITE 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR HO	72097-06
72097-00007-04	TENSOPLUS COHESIVE 10CM X 3M WHITE 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR HO	72097-07
72097-00008-04	TENSOPLUS COHESIVE 8CM X 3M TAN 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR HO	72097-08
72097-00009-04	TENSOPLUS COHESIVE 10CM X 3M TAN 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR HO	72097-09
72097-00011-04	TENSOPLUS COHESIVE 8CM X 3M WHITE 1 FR EN IT CS	72097-11
72097-00012-04	TENSOPLUS COHESIVE 10CM X 3M WHITE 1 FR EN IT CS	72097-12
72097-00013-04	TENSOPLUS COHESIVE 8CM X 3M TAN 1 FR EN IT CS	72097-13
72097-00014-04	TENSOPLUS COHESIVE 10CM X 3M TAN 1 FR EN IT CS	72097-14