

Declaration of Conformity Strappal® Forte

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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:

Strappal® Forte

Basic UDI-DI:

40428094003619193

Intended purpose:

Strappal® Forte is intended for functional taping as

treatment and prevention of injuries to muscles, ligaments and joints. It's intended for rigid immobilization and for

sports injuries (strains and sprains).
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:

Classification:

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:

VIBRAME, 08.11.2024 Philipped Hatet Senio Project Manager BSN Medical SAS



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Article	Description	REF
73444-00000-02	STRAPPAL FORTE 2CM X 10M WHITE 1 CS DA NL EN FI FR DE IT NO PT ES SV	73444-00
73444-00001-02	STRAPPAL FORTE 3.75CM X 10M WHITE 1 CS DA NL EN FI FR DE IT NO PT ES SV	73444-01
73444-00002-02	STRAPPAL FORTE 5CM X 10M WHITE 1 CS DA NL EN FI FR DE IT NO PT ES SV	73444-02