

Declaration of Conformity Extensoplast®

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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:

Extensoplast®

Basic UDI-DI:

4042809400364899X

Intended purpose:

Extensoplast® is intended for compressive

strapping/taping and fixation purposes. Application fields

- 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 improvementElasto-compressive treatment in phlebology

The device is non-sterile and for single application use

Intended users are healthcare 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: 12.12.2024

Compiled and released:

VIBRAVE, 12.12.2024 Philippe Hatet Senior Project Manager BSN Medical SAS



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Article	Description	REF
72057-00000-02	EXTENSOPLAST 6CM X 2.5M 1 FR HO	72057-00
72057-00001-02	EXTENSOPLAST 6CM X 2.5M 1 FR PH	72057-01
72057-00002-02	EXTENSOPLAST 8CM X 2.5M 1 FR HO	72057-02
72057-00003-02	EXTENSOPLAST 8CM X 2.5M 1 FR PH	72057-03
72057-00004-02	EXTENSOPLAST 10CM X 2.5M 1 FR HO	72057-04
72057-00005-02	EXTENSOPLAST 10CM X 2.5M 1 FR PH	72057-05