

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:

Extensoplast®

Basic UDI-DI:

4042809400364899X

Intended purpose:

Extensoplast® is intended for compressive

strapping/taping and 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

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.

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Compiled and released:

VIBRAME, 29.09.2020 Philipped Hatet Site Manager Vibraye BSN Medical SAS



Declaration of Conformity Extensoplast®

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