We,

BSN Medical SAS
Rue du Millenaire / CS 90022
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).

Prduct Name:	**Biplatrix®**
Basic UDI-DI:	**4042809400419379D**
Intended purpose:	**Biplatrix (white) is intended for all kind of plaster cast for orthopaedic and traumatology. The device is non-sterile and for single use (bandage) and single application (splint). Intended duration of usage is depending on the purpose of the immobilization treatment and can vary between a couple of days and several weeks. Intended Users are Health Care Professionals. 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.

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Philippe Hatet
Senior Project Manager
BSN Medical SAS

Article	Description	REF
02918-00000-04	BIPLATRIX 12CM X 25M WHITE 1 DE EN FR NL	02918-00
02919-00000-04	BIPLATRIX 10CM X 25M WHITE 1 DE EN FR NL	02919-00
02920-00000-04	BIPLATRIX 15CM X 25M WHITE 1 DE EN FR NL	02920-00
02921-00000-05	BIPLATRIX 20CM X 25M WHITE 1 DE EN FR NL	02921-00