

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:

Platrix®

Basic UDI-DI:

40428094004194092

Intended purpose:

Platrix is intended for all kind of plaster cast for orthopedic 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

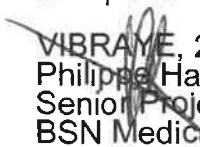
Classification:

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.

Declaration of conformity issued: 21.10.2024

Compiled and released:


VIBRAYE, 21.10.2024
Philippe Hatet
Senior Project Manager
BSN Medical SAS

Article	Description	REF
02973-00000-04	PLATRIX LONGETTE 10CM X 25M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR	02973-00
02974-00000-04	PLATRIX LONGETTE 12CM X 25M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR	02974-00
02975-00000-04	PLATRIX LONGETTE 15CM X 25M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR	02975-00
02976-00000-04	PLATRIX LONGETTE 20CM X 25M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR	02976-00
71997-00000-02	PLATRIX SLAB EN DE FR ES PT IT NL SV NO DA FI ZH AR ATT.20MX10CM(4)ITALIE	71997-00
71997-00001-02	PLATRIX SLAB EN DE FR ES PT IT NL SV NO DA FI ZH AR ATT.20MX12CM(4)ITALIE	71997-01
71997-00002-02	PLATRIX SLAB EN DE FR ES PT IT NL SV NO DA FI ZH AR ATT.20MX15CM(4)ITALIE	71997-02
71997-00003-02	PLATRIX SLAB EN DE FR ES PT IT NL SV NO DA FI ZH AR ATT.20MX20CM(4)ITALIE	71997-03