

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: **Platrix®**
Basic UDI-DI: **40428094003643394**

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.

Date of Issue: 08.04.2020

Compiled and released:

VIBRAYE, 08.04.2020
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Site Manager Vibraye
BSN Medical SAS



Article	Description	REF
02924-00000-04	PLATRIX 5CM X 3M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10PKS X 4)	02924-00
02925-00000-04	PLATRIX 8CM X 3M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10PKS X 2)	02925-00
02926-00000-04	PLATRIX 10CM X3M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10PKS X 2)	02926-00
02927-00000-04	PLATRIX 12CM X 3M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10PKS X 2)	02927-00
02928-00000-04	PLATRIX 15CM X 3M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10PKS X 2)	02928-00
02929-00000-04	PLATRIX 20CM X 3M 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (5PKS X 2)	02929-00
02983-00000-04	PLATRIX 6CM X 2M WHITE 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10PKS X 2BAN IN FOIL)	02983-00
02984-00000-04	PLATRIX 8CM X 2M WHITE 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10PKS X 2BAN IN FOIL)	02984-00
02985-00000-04	PLATRIX 10CM X 2M WHITE 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10PKS X 2BAN IN FOIL)	02985-00
02986-00000-04	PLATRIX 12CM X 2M WHITE 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10PKS X 2BAN IN FOIL)	02986-00
02987-00000-04	PLATRIX 15CM X 2 M WHITE 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR (10PKS X 2BAN IN FOIL)	02987-00
71996-00001-01	PLATRIX LINEAR 6CM X 2M 20 EN DE FR ES PT IT NL SV NO DA FI ZH AR	71996-01
71996-00003-01	PLATRIX LINEAR 15CM X 4M 40 EN DE FR ES PT IT NL SV NO DA FI ZH AR	71996-03
71996-00004-01	PLATRIX LINEAR 10CM X 2M 40 EN DE FR ES PT IT NL SV NO DA FI ZH AR BLC	71996-04
71996-00005-01	PLATRIX LINEAR 15CM X 2M 40 EN DE FR ES PT IT NL SV NO DA FI ZH AR BLC	71996-05
71996-00006-01	PLATRIX LINEAR 20CM X 2M 20 EN DE FR ES PT IT NL SV NO DA FI ZH AR BLC	71996-06
71996-00007-01	PLATRIX LINEAR 5CM X 3M 40 EN DE FR ES	71996-07

Article	Description	REF
	PT IT NL SV NO DA FI ZH AR	
71996-00009-01	PLATRIX LINEAR 10CM X 3M 40 EN DE FR ES PT IT NL SV NO DA FI ZH AR	71996-09
71996-00011-01	PLATRIX LINEAR 15CM X 3M 40 EN DE FR ES PT IT NL SV NO DA FI ZH AR	71996-11
71996-00013-01	PLATRIX LINEAR 20CM X 3M 20 EN DE FR ES PT IT NL SV NO DA FI ZH AR	71996-13
71996-00015-01	PLATRIX LINEAR 60CM X 3M 4 AR ZH DA NL EN FI FR DE IT NO PT ES SV	71996-15
71996-00016-01	PLATRIX 10CM X 2M 10 AR ZH DA NL EN FI FR DE IT NO PT ES SV	71996-16
71996-00017-01	PLATRIX 15CM X 2M 10 AR ZH DA NL EN FI FR DE IT NO PT ES SV	71996-17
71996-00018-01	PLATRIX 20CM X 2M 10 AR ZH DA NL EN FI FR DE IT NO PT ES SV	71996-18
71996-00019-01	PLATRIX 30CM X 3M 20 EN DE FR ES PT IT NL SV NO DA FI ZH AR	71996-19
71996-00023-01	PLATRIX 8CM X 2M 20 EN DE FR ES PT IT NL SV NO DA FI ZH AR	71996-23
71996-00024-01	PLATRIX 6CM X 3M 40 EN DE FR ES PT IT NL SV NO DA FI ZH AR	71996-24
71996-00026-01	PLATRIX 10CM X 4M 40 EN DE FR ES PT IT NL SV NO DA FI ZH AR	71996-26
71996-00028-01	PLATRIX 20CM X 4M WHITE 20 EN DE FR ES PT IT NL SV NO DA FI ZH AR	71996-28

