

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:

**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.

Declaration of conformity issued: 21.10.2024

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Compiled and released:

VIBRAYE, 21.10.2024  
Philippe Hatet  
Senior Project Manager  
BSN Medical SAS

| Article        | Description                                                                                     | REF      |
|----------------|-------------------------------------------------------------------------------------------------|----------|
| 02924-00000-05 | PLATRIX 5CM X 3M WHITE 1 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR (10PKS X 4)                  | 02924-00 |
| 02925-00000-05 | PLATRIX 8CM X 3M WHITE 1 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR (10PKS X 2)                  | 02925-00 |
| 02926-00000-05 | PLATRIX 10CM X 3M WHITE 1 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR (10PKS X 2)                 | 02926-00 |
| 02927-00000-05 | PLATRIX 12CM X 3M WHITE 1 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR (10PKS X 2)                 | 02927-00 |
| 02928-00000-05 | PLATRIX 15CM X 3M WHITE 1 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR (10PKS X 2)                 | 02928-00 |
| 02929-00000-05 | PLATRIX 20CM X 3M WHITE 1 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR (5PKS X 2)                  | 02929-00 |
| 02983-00000-05 | PLATRIX 6CM X 2M WHITE 1 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR (10PKS X 2BAN IN<br>FOIL)    | 02983-00 |
| 02984-00000-05 | PLATRIX 8CM X 2M WHITE 1 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR (10PKS X 2BAN IN<br>FOIL)    | 02984-00 |
| 02985-00000-05 | PLATRIX 10CM X 2M WHITE 1 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR (10PKS X 2BAN IN<br>FOIL)   | 02985-00 |
| 02986-00000-05 | PLATRIX 12CM X 2M WHITE 1 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR (10PKS X 2BAN IN<br>FOIL)   | 02986-00 |
| 02987-00000-05 | PLATRIX 15CM X 2 M WHITE 1 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR (10PKS X 2BAN IN<br>FOIL)  | 02987-00 |
| 71996-00001-02 | PLATRIX LINEAR 6CM X 2M WHITE 20 EN DE<br>FR ES PT IT NL SV NO DA FI ZH AR<br>(2BDGES/PACK)     | 71996-01 |
| 71996-00003-02 | PLATRIX LINEAR 15CM X 4M WHITE 40 EN DE<br>FR ES PT IT NL SV NO DA FI ZH AR<br>(2BDGES/PACK)    | 71996-03 |
| 71996-00004-02 | PLATRIX LINEAR 10CM X 2M WHITE 40 EN DE<br>FR ES PT IT NL SV NO DA FI ZH AR BLC<br>(2BDGES/PCK) | 71996-04 |
| 71996-00005-02 | PLATRIX LINEAR 15CM X 2M WHITE 40 EN DE<br>FR ES PT IT NL SV NO DA FI ZH AR BLC<br>(2BDGES/PCK) | 71996-05 |

| Article        | Description                                                               | REF      |
|----------------|---------------------------------------------------------------------------|----------|
| 71996-00006-02 | PLATRIX LINEAR 20CM X 2M 20 EN DE FR ES<br>PT IT NL SV NO DA FI ZH AR BLC | 71996-06 |
| 71996-00007-02 | PLATRIX LINEAR 5CM X 3M 40 EN DE FR ES PT<br>IT NL SV NO DA FI ZH AR      | 71996-07 |
| 71996-00009-02 | PLATRIX LINEAR 10CM X 3M 40 EN DE FR ES<br>PT IT NL SV NO DA FI ZH AR     | 71996-09 |
| 71996-00011-02 | PLATRIX LINEAR 15CM X 3M 40 EN DE FR ES<br>PT IT NL SV NO DA FI ZH AR     | 71996-11 |
| 71996-00013-02 | PLATRIX LINEAR 20CM X 3M 20 EN DE FR ES<br>PT IT NL SV NO DA FI ZH AR     | 71996-13 |
| 71996-00019-02 | PLATRIX 30CM X 3M 20 EN DE FR ES PT IT NL<br>SV NO DA FI ZH AR            | 71996-19 |
| 71996-00023-02 | PLATRIX 8CM X 2M 20 EN DE FR ES PT IT NL<br>SV NO DA FI ZH AR             | 71996-23 |
| 71996-00024-02 | PLATRIX 6CM X 3M 40 EN DE FR ES PT IT NL<br>SV NO DA FI ZH AR             | 71996-24 |
| 71996-00026-02 | PLATRIX 10CM X 4M 40 EN DE FR ES PT IT NL<br>SV NO DA FI ZH AR            | 71996-26 |
| 71996-00028-02 | PLATRIX 20CM X 4M WHITE 20 EN DE FR ES<br>PT IT NL SV NO DA FI ZH AR      | 71996-28 |
| 71996-00040-00 | PLATRIX 10CM X 2M 1 AR ZH DA NL EN FI FR<br>DE IT NO PT ES SV             | 71996-40 |
| 71996-00041-00 | PLATRIX 15CM X 2M 1 AR ZH DA NL EN FI FR<br>DE IT NO PT ES SV             | 71996-41 |
| 71996-00042-00 | PLATRIX 20CM X 2M 1 AR ZH DA NL EN FI FR<br>DE IT NO PT ES SV             | 71996-42 |

