

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:

Acrylastic®

Basic UDI-DI:

4042809400362689D

Intended purpose:

Acrylastic® is intended for compressive strapping/taping and dressing 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 only. Intended Users are Health Care Professionals and Patients. 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: 22.11.2024

Compiled and released:


VIBRAYE, 22.11.2024
Philippe Hatet
Senior Project Manager
BSN Medical SAS

Article	Description	REF
02406-00000-09	ACRYLASTIC 6CM X 2.5M TAN 1 EN FR ES IT NL PT SV NO DA FI SL AR ZH	02406-00
02408-00000-09	ACRYLASTIC 8CM X 2.5M TAN 1 EN FR ES IT NL PT SV NO DA FI SL AR ZH	02408-00
02410-00000-09	ACRYLASTIC 10CM X 2.5M TAN 1 EN FR ES IT NL PT SV NO DA FI SL AR ZH	02410-00
02697-00000-03	ACRYLASTIC 6CMX 2.5M TAN 1 DE FR IT	02697-00
02698-00000-03	ACRYLASTIC 8CM X 2.5M TAN 1 DE FR IT	02698-00
02699-00000-03	ACRYLASTIC 10CM X 2.5M TAN 1 DE FR IT	02699-00
02700-00000-03	ACRYLASTIC 6CM X 2.5M TAN 1 DE FR IT 12/BOX	02700-00
02701-00000-03	ACRYLASTIC 8CM X 2.5M TAN 1 DE FR IT 12/BOX	02701-00
02702-00000-03	ACRYLASTIC 10CM X 2.5M TAN 1 DE FR IT 12/BOX	02702-00
47190-00000-04	ACRYLASTIC 6CMX2.5M (4.5M) TAN 1 EN FR ES IT NL PT SV NO DA FI SL AR ZH	47190-00
47191-00000-04	ACRYLASTIC 8CMX2.5M (4.5M) TAN 1 EN FR ES IT NL PT SV NO DA FI SL AR ZH	47191-00
47192-00000-04	ACRYLASTIC 10CMX2.5M (4.5M) TAN 1 EN FR ES IT NL PT SV NO DA FI SL AR ZH	47192-00