

We,

BSN Medical SAS
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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:

Optiplaste® C

Basic UDI-DI:

4042809400363238U

Intended purpose:

Optiplaste C 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.

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BSN Medical SAS

Article	Description	REF
02506-00000-08	OPTIPLASTE C 6CM X 2.5M TAN 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR EP	02506-00
02508-00000-08	OPTIPLASTE C 8CM X 2.5M TAN 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR EP	02508-00
02510-00000-08	OPTIPLASTE C 10CM X 2.5M TAN 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR EP	02510-00
47186-00000-03	OPTIPLASTE C 6CM X 2.5M TAN 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR AP 12/BOX	47186-00
47187-00000-03	OPTIPLASTE C 8CM X 2.5M TAN 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR AP 12/BOX	47187-00
47188-00000-03	OPTIPLASTE C 10CM X 2.5M TAN 1 EN DE FR ES PT IT NL SV NO DA FI ZH AR AP 12/BOX	47188-00