

Declaration of Conformity Lightplast®

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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:

Lightplast®

Basic UDI-DI:

4042809400363128P

Intended purpose:

Lightplast Pro (white) 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 duration of usage for not more than 30 days. Intended users are Health Care Professionals and Patients. The use of the product is not restricted to a specific population.

Conformity assessment route: Annex II+III

Classification rule:

Classification:

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: 03.10.2024

Compiled and released:

VIBRAYE, 03.10.2024 Philippe Hatet Senior Project Manager BSN Medical SAS



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Article	Description	REF
76952-00000-05	LIGHTPLAST PRO 2.5CM X 2.35M WHITE 48 NL EN FI FR DE EL IT NO PT ES	76952-00
76953-00000-05	LIGHTPLAST PRO 3.75CM X 2.35M WHITE 1 NL EN FI FR DE EL IT NO PT ES 32/CASE	76953-00
76954-00000-05	LIGHTPLAST PRO 5CM X 2.35M WHITE 1 AR ZH CS DA NL EN FI FR DE IT NO PT ES SV 24/CASE	76954-00
76955-00000-05	LIGHTPLAST PRO 7.5CM X 2.35M WHITE 1 AR ZH CS DA NL EN FI FR DE IT NO PT ES SV 16/CASE	76955-00
76956-00000-05	LIGHTPLAST PRO 5CM X 6.8M WHITE 1 AR ZH CS DA NL EN FI FR DE IT NO PT ES SV 24/CASE	76956-00
76957-00000-05	LIGHTPLAST PRO 7.5CM X 6.8M WHITE 1 AR ZH CS DA NL EN FI FR DE IT NO PT ES SV 16/CASE	76957-00