

We,

**BSN medical Inc.
5825 Carnegie Blvd.
28209 Charlotte,
USA
(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: **GELOCAST**
Basic UDI-DI: **4042809400352438N**

Intended purpose: **Gelocast® is intended to be used for compression bandages for phlebological indications, for support and relief bandages for diseases of the ligament and postural system.**

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.

European Authorized Representative:

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Date of Issue: 23.11.2020

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Compiled and released:

Charlotte,, 23.11.2020
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
01078-00000-06	GELOCAST 7CM X 10MTR TAN 1 DE EN FR ES PT NL JA IT	01078-00
01079-00000-07	GELOCAST 10CM X 10MTR TAN 1 DE EN FR ES PT NL JA IT	01079-00