

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: **GELOSTRETCH**
Basic UDI-DI: **4042809400395139Q**

Intended purpose: **Gelostretch® 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:

**BSN medical GmbH
Quickbornstrasse 24
20253 Hamburg
Germany
(SRN: NOT ISSUED YET)**

Date of Issue: 08/13/2020

Karla Worley-Ham

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Compiled and released:

Charlotte,, 08/13/2020
Karla Worley-Ham
Director Regulatory Affairs, LM NA
BSN medical Inc.

Article	Description	REF
45043-00000-04	GELOSTRETCH 8CM X 7MTR TAN 1 DE EN FR ES PT NL IT	45043-00
45291-00000-04	GELOSTRETCH 8CM X 7MTR TAN 10 DE EN FR ES PT NL IT GR TR	45291-00
45292-00000-04	GELOSTRETCH 10CM X 5MTR TAN 1 DE EN FR ES PT NL	45292-00
45293-00000-04	GELOSTRETCH 10CM X 7MTR TAN 1 DE EN FR ES PT NL	45293-00
45294-00000-04	GELOSTRETCH 10CM X 10MTR TAN 1 DE EN FR ES PT NL	45294-00
45295-00000-04	GELOSTRETCH 10CM X 5MTR TAN 10 DE EN FR ES PT NL IT	45295-00
45296-00000-04	GELOSTRETCH 10CM X 7MTR TAN 10 DE EN FR ES PT NL IT GR PL	45296-00
45297-00000-04	GELOSTRETCH 10CM X 10MTR TAN 1 DE EN FR ES PT NL IT	45297-00