

We,

**BSN medical Inc.
5825 Carnegie Blvd.
28209 Charlotte,
USA
(SRN: US-MF-000019174)**

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:

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:

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Classification:

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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
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(SRN: DE-AR-000005791)**

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Charlotte,, 08.06.2023
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Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
45043-00000-05	GELOSTRETCH 8CM X 7MTR TAN 1 DE EN FR ES PT NL IT	45043-00
45291-00000-05	GELOSTRETCH 8CM X 7MTR TAN 1 DE EN FR ES PT NL IT GR TR	45291-00
45292-00000-05	GELOSTRETCH 10CM X 5MTR TAN 1 DE EN FR ES PT NL	45292-00
45293-00000-05	GELOSTRETCH 10CM X 7MTR TAN 1 DE EN FR ES PT NL	45293-00
45294-00000-05	GELOSTRETCH 10CM X 10MTR TAN 1 DE EN FR ES PT NL	45294-00
45295-00000-05	GELOSTRETCH 10CM X 5MTR TAN 1 DE EN FR ES PT NL IT	45295-00
45296-00000-05	GELOSTRETCH 10CM X 7MTR TAN 1 DE EN FR ES PT NL IT GR PL	45296-00
45297-00000-05	GELOSTRETCH 10CM X 10MTR TAN 1 DE EN FR ES PT NL IT	45297-00