

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:

GELOCAST ELASTIC

Basic UDI-DI:

4042809400395109J

Intended purpose:

Gelocast® elastic 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
45090-00000-03	GELOCAST ELASTIC 8CM X 7MTR 1 DE EN FR ES PT NL JA IT	45090-00
45091-00000-03	GELOCAST ELASTIC 8CM X 10MTR 1 DE EN FR ES PT NL	45091-00
45092-00000-03	GELOCAST ELASTIC 10CM X 7MTR 1 DE EN FR ES PT NL JA	45092-00
45094-00000-03	GELOCAST ELASTIC 10CM X 10MTR 1 DE EN FR ES PT NL JA	45094-00