

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:

Delta-Solo® Straps

Basic UDI-DI:

40428094004222488

Intended purpose:

Delta-Solo Straps are intended for securing post-operative shoes in fracture management environment. Application fields include casting & splinting procedures.

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
Schützenstr. 1-3
22761 Hamburg
Germany
(SRN: DE-AR-000005791)**

Declaration of conformity issued: 02.02.2024

Andreas Matthies

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Compiled and released:

Charlotte,, 02.02.2024
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
72298-00017-02	DELTA-SOLO STRAP 40CM 20	72298-17
72298-00018-02	DELTA-SOLO STRAP 50CM 20	72298-18
72298-00019-02	DELTA-SOLO STRAP 60CM 20	72298-19