

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-Rol®

Basic UDI-DI:

404280940038478A8

Intended purpose:

**DELTA ROL is intended for padding purposes.
Application fields include casting & splinting procedures,
compression therapy and cushioning in prosthetics.**

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

Date of Issue: 26.09.2023

Andreas Matthies

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Date: 2023.09.26 10:25:39 +02'00'

Compiled and released:

Charlotte,, 26.09.2023
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
72310-00000-04	DELTA-ROL 5CM X 2.75M 12 AR ZH CS DA NL EN FI FR IT NO PT ES SV	72310-00
72310-00001-04	DELTA-ROL 7.5CM X 2.75M 12 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72310-01
72310-00002-04	DELTA-ROL 10CM X 2.75M 12 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72310-02
72310-00003-04	DELTA-ROL 15CM X 2.75M 12 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72310-03
72310-00004-04	DELTA-ROL 20CM X 2.75M 6 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72310-04