

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-Lite® Conformable

Basic UDI-DI:

404280940035996AE

Intended purpose:

Delta-Lite® Conformable casting tape is intended to be used for external rigid immobilization through casting and/or 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)

Date of Issue: 01.11.2023

Andreas Matthies

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Compiled and released:

Charlotte,, 01.11.2023
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
72265-00000-03	DELTA-LITE CONFORMABLE 5CM X 3.6M RED 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72265-00
72265-00001-03	DELTA-LITE CONFORMABLE 7.5CM X 3.6M RED 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72265-01
72265-00002-03	DELTA-LITE CONFORMABLE 10CM X 3.6M RED 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72265-02
72266-00000-03	DELTA-LITE CONFORMABLE 5CM X 3.6M DEEP BLUE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72266-00
72266-00001-03	DELTA-LITE CONFORMABLE 7.5CM X 3.6M DEEP BLUE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72266-01
72266-00002-03	DELTA-LITE CONFORMABLE 10CM X 3.6M DEEP BLUE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72266-02
72267-00000-03	DELTA-LITE CONFORMABLE 5CM X 3.6M GREEN 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72267-00
72267-00001-03	DELTA-LITE CONFORMABLE 7.5CM X 3.6M GREEN 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72267-01
72267-00002-03	DELTA-LITE CONFORMABLE 10CM X 3.6M GREEN 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72267-02
72268-00000-03	DELTA-LITE CONFORMABLE 5CM X 3.6M PURPLE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72268-00
72268-00001-03	DELTA-LITE CONFORMABLE 7.5CM X 3.6M PURPLE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72268-01
72268-00002-03	DELTA-LITE CONFORMABLE 10CM X 3.6M PURPLE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72268-02
72269-00000-03	DELTA-LITE CONFORMABLE 5CM X 3.6M BLACK 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72269-00

Article	Description	REF
72269-00001-03	DELTA-LITE CONFORMABLE 7.5CM X 3.6M BLACK 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72269-01
72269-00002-03	DELTA-LITE CONFORMABLE 10CM X 3.6M BLACK 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72269-02
72270-00000-03	DELTA-LITE CONFORMABLE 5CM X 3.6M WHITE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72270-00
72270-00001-03	DELTA-LITE CONFORMABLE 7.5CM X 3.6M WHITE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72270-01
72270-00002-03	DELTA-LITE CONFORMABLE 10CM X 3.6M WHITE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72270-02
72270-00003-03	DELTA-LITE CONFORMABLE 12.5CM X 3.6M WHITE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72270-03
72271-00000-03	DELTA-LITE CONFORMABLE 5CM X 3.6M LIGHT BLUE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-00
72271-00001-03	DELTA-LITE CONFORMABLE 7.5CM X 3.6M LIGHT BLUE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-01
72271-00002-03	DELTA-LITE CONFORMABLE 10CM X 3.6M LIGHT BLUE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-02
72271-00003-03	DELTA-LITE CONFORMABLE 5CM X 3.6M NEON ORANGE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-03
72271-00004-03	DELTA-LITE CONFORMABLE 7.5CM X 3.6M NEON ORANGE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-04
72271-00005-03	DELTA-LITE CONFORMABLE 10CM X 3.6M NEON ORANGE 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-05
72271-00006-03	DELTA-LITE CONFORMABLE 5CM X 3.6M NEON YELLOW 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-06

Article	Description	REF
72271-00007-03	DELTA-LITE CONFORMABLE 7.5CM X 3.6M NEON YELLOW 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-07
72271-00008-03	DELTA-LITE CONFORMABLE 10CM X 3.6M NEON YELLOW 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-08
72271-00010-03	DELTA-LITE CONFORMABLE 5CM X 3.6M NEON PINK 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-10
72271-00011-03	DELTA-LITE CONFORMABLE 7.5CM X 3.6M NEON PINK 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-11
72271-00012-03	DELTA-LITE CONFORMABLE 10CM X 3.6M NEON PINK 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72271-12
72343-00000-03	DELTA-LITE CONFORMABLE MIXED PACK 5CM X 3.6M ASSORTED COLOURS 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72343-00
72343-00001-03	DELTA-LITE CONFORMABLE MIXED PACK 7.5CM X 3.6M ASSORTED COLOURS 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72343-01
72343-00002-03	DELTA-LITE CONFORMABLE MIXED PACK 10CM X 3.6M ASSORTED COLOURS 10 AR ZH DA NL EN FI FR DE IT JA NO PT ES SV	72343-02