

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-Cast® Elite

Basic UDI-DI:

404280940034889A5

Intended purpose:

Delta-Cast® Elite casting tape is intended 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
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(SRN: DE-AR-000005791)**

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Compiled and released:

Charlotte,, 10.05.2022
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
72275-00000-02	DELTA CAST ELITE 5CM X 3.6M RED 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72275-00
72275-00001-02	DELTA CAST ELITE 7.5CM X 3.6M RED 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72275-01
72275-00002-02	DELTA CAST ELITE 10CM X 3.6M RED 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72275-02
72276-00000-02	DELTA CAST ELITE 5CM X 3.6M DEEP BLUE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72276-00
72276-00001-02	DELTA CAST ELITE 7.5CM X 3.6M DEEP BLUE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72276-01
72276-00002-02	DELTA CAST ELITE 10CM X 3.6M DEEP BLUE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72276-02
72276-00003-01	DELTA CAST ELITE 12.5CM X 3.6M DEEP BLUE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72276-03
72277-00000-02	DELTA CAST ELITE 5CM X 3.6M PURPLE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72277-00
72277-00001-02	DELTA CAST ELITE 7.5CM X 3.6M PURPLE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72277-01
72277-00002-02	DELTA CAST ELITE 10CM X 3.6M PURPLE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72277-02
72278-00000-02	DELTA CAST ELITE 5CM X 3.6M BLACK 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72278-00
72278-00001-02	DELTA CAST ELITE 7.5CM X 3.6M BLACK 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72278-01
72278-00002-02	DELTA CAST ELITE 10CM X 3.6M BLACK 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72278-02
72279-00000-02	DELTA CAST ELITE 5CM X 3.6M WHITE 10 AR	72279-00

Article	Description	REF
	ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	
72279-00001-02	DELTA CAST ELITE 7.5CM X 3.6M WHITE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72279-01
72279-00002-02	DELTA CAST ELITE 10CM X 3.6M WHITE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72279-02
72279-00003-02	DELTA CAST ELITE 12.5CM X 3.6M WHITE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72279-03
72279-00004-02	DELTA CAST ELITE 2.5CM X 1.8M WHITE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	72279-04
72279-00010-03	DELTA CAST ELITE 5CM X 3.6M WHITE 1 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV LPPR	72279-10
72279-00011-03	DELTA CAST ELITE 7.5CM X 3.6M WHITE 1 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV LPPR	72279-11
72279-00012-03	DELTA CAST ELITE 10CM X 3.6M WHITE 1 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV LPPR	72279-12
72279-00013-03	DELTA CAST ELITE 12.5CM X 3.6M WHITE 1 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV LPPR	72279-13
72279-00014-03	DELTA CAST ELITE 2.5CM X 1.8M WHITE 1 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV LPPR	72279-14
73453-00000-01	DELTA CAST ELITE 5CM X 3.6M LIGHT BLUE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73453-00
73453-00001-01	DELTA CAST ELITE 7.5CM X 3.6M LIGHT BLUE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73453-01
73453-00002-01	DELTA CAST ELITE 10CM X 3.6M LIGHT BLUE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73453-02
73454-00000-01	DELTA CAST ELITE 5CM X 3.6M GREEN 10 AR	73454-00

Article	Description	REF
	ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	
73454-00001-01	DELTA CAST ELITE 7.5CM X 3.6M GREEN 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73454-01
73454-00002-01	DELTA CAST ELITE 10CM X 3.6M GREEN 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73454-02
73455-00000-02	DELTA CAST ELITE 5CM X 3.6M PINK 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73455-00
73455-00001-02	DELTA CAST ELITE 7.5CM X 3.6M PINK 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73455-01
73455-00002-02	DELTA CAST ELITE 10CM X 3.6M PINK 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73455-02
73456-00000-01	DELTA CAST ELITE 5CM X 3.6M NEON ORANGE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73456-00
73456-00001-01	DELTA CAST ELITE 7.5CM X 3.6M NEON ORANGE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73456-01
73456-00002-01	DELTA CAST ELITE 10CM X 3.6M NEON ORANGE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73456-02
73457-00000-01	DELTA CAST ELITE MIXED PACK 5CM X 3.6M MULTI 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73457-00
73457-00001-01	DELTA CAST ELITE MIXED PACK 7.5CM X 3.6M MULTI 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73457-01
73457-00002-01	DELTA CAST ELITE MIXED PACK 10CM X 3.6M MULTI 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	73457-02
74545-00003-01	DELTA CAST ELITE SLAB 10CMX38CM 5PLY WHITE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	74545-03
74545-00004-01	DELTA CAST ELITE SLAB 10CMX90CM 5PLY WHITE 10 AR ZH CS DA NL EN FI FR DE IT JA	74545-04

Article	Description	REF
	NO PT RO ES SV	
74545-00005-01	DELTA CAST ELITE SLAB 12.5CMX90CM 5PLY WHITE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	74545-05
74545-00006-01	DELTA CAST ELITE SLAB 7.5CM X 76CM 3PLY WHITE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	74545-06
74545-00007-01	DELTA CAST ELITE SLAB 5CM X 20CM 3PLY WHITE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	74545-07
74545-00008-01	DELTA CAST ELITE SLAB 7.5CM X 20CM 3PLY WHITE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	74545-08
74545-00009-01	DELTA CAST ELITE SLAB 7.5CM X 38CM 3PLY WHITE 10 AR ZH CS DA NL EN FI FR DE IT JA NO PT RO ES SV	74545-09