

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® Soft

Basic UDI-DI:

4042809400352398X

Intended purpose:

Delta-Cast® Soft casting tape is intended for external rigid immobilization through casting or functional casting 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: 05.02.2024

Andreas Matthies

Digitally signed by dehanta
DN: dc=net, dc=ecdomain, ou=EU, ou=DE, ou=HAM,
ou=C3113016, ou=Users, cn=dehanta,
email=andreas.matthies@essity.com
Date: 2024.02.05 11:06:59 +01'00'

Compiled and released:

Charlotte,, 05.02.2024
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
72708-00001-03	DELTA-CAST SOFT 5CM X 3.6M BLACK 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-01
72708-00002-03	DELTA-CAST SOFT 2.5CM X 1.8M WHITE 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-02
72708-00005-03	DELTA-CAST SOFT 5CM X 3.6M BLUE 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-05
72708-00008-03	DELTA-CAST SOFT 5CM X 3.6M RED 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-08
72708-00009-03	DELTA-CAST SOFT 5CM X 3.6M PAW 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-09
72708-00011-03	DELTA-CAST SOFT 7.5CM X 3.6M BLACK 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-11
72708-00012-03	DELTA-CAST SOFT 5CM X 3.6M WHITE 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-12
72708-00015-03	DELTA-CAST SOFT 7.5CM X 3.6M BLUE 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-15
72708-00018-03	DELTA-CAST SOFT 7.5CM X 3.6M RED 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-18
72708-00019-03	DELTA-CAST SOFT 7.5CM X 3.6M PAW 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-19
72708-00021-03	DELTA-CAST SOFT 10CM X 3.6M BLACK 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-21
72708-00022-03	DELTA-CAST SOFT 7.5CM X 3.6M WHITE 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-22
72708-00025-03	DELTA-CAST SOFT 10CM X 3.6M BLUE 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-25
72708-00028-03	DELTA-CAST SOFT 10CM X 3.6M RED 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-28
72708-00029-03	DELTA-CAST SOFT 10CM X 3.6M PAW 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-29
72708-00032-03	DELTA-CAST SOFT 10CM X 3.6M WHITE 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-32
72708-00035-03	DELTA-CAST SOFT 2.5CM X 1.8M BLUE 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-35
72708-00042-03	DELTA-CAST SOFT 12.5CM X 3.6M WHITE 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-42
72708-00050-03	DELTA-CAST SOFT 5CM X 3.6M PINK 10 AR ZH	72708-50

Article	Description	REF
	DA NL EN FI FR DE EL IT NO PT ES SV	
72708-00051-03	DELTA-CAST SOFT 7.5CM X 3.6M PINK 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-51
72708-00052-03	DELTA-CAST SOFT 10CM X 3.6M PINK 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-52
72708-00060-03	DELTA-CAST SOFT 5CM X 3.6M HEARTS 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-60
72708-00061-03	DELTA-CAST SOFT 7.5CM X 3.6M HEARTS 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	72708-61
72708-00090-03	DELTA-CAST SOFT MIXED PACK 5CM X 3.6MTR MULTI 10 DA NL EN FI FR DE EL IT JA NO PT ES SV	72708-90
72708-00091-03	DELTA-CAST SOFT MIXED PACK 7.5CM X 3.6MTR MULTI 10 DA NL EN FI FR DE EL IT JA NO PT ES SV	72708-91
73459-00018-03	DELTA-CAST SOFT 5CM X 3.6M ORANGE 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	73459-18
73459-00019-03	DELTA-CAST SOFT 7.5CM X 3.6M ORANGE 10 AR ZH DA NL EN FI FR DE EL IT NO PT ES SV	73459-19