

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-Dry®

Basic UDI-DI:

4042809400430878V

Intended purpose:

Delta-Dry is intended for professional use in padding purposes. Application fields include casting and splinting procedures.

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)**

Declaration of conformity issued: 18.03.2024

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Digitally signed by

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Date: 2024.03.18 19:08:35 +01'00'

Compiled and released:

Charlotte,, 18.03.2024
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
73443-00000-04	DELTA-DRY WATER RESISTANT PADDING 5CM X 2.4M WHITE 12 DA NL EN FI FR DE EL IT NO PT ES SV	73443-00
73443-00001-04	DELTA-DRY WATER RESISTANT PADDING 7.5CM X 2.4M WHITE 12 DA NL EN FI FR DE EL IT NO PT ES SV	73443-01
73443-00002-04	DELTA-DRY WATER RESISTANT PADDING 10CM X 2.4M WHITE 12 DA NL EN FI FR DE EL IT NO PT ES SV	73443-02
73443-00012-04	DELTA-DRY WATER RESISTANT PADDING 5CM X 2.4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV LPPR	73443-12
73443-00013-04	DELTA-DRY WATER RESISTANT PADDING 7.5CM X 2.4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV LPPR	73443-13
73443-00014-04	DELTA-DRY WATER RESISTANT PADDING 10CM X 2.4M WHITE 1 DA NL EN FI FR DE EL IT NO PT ES SV LPPR	73443-14