

We,

**BSN medical GmbH
Schützenstr. 1-3
22761 Hamburg
Germany
(SRN: DE-MF-000005787)**

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-Xpress™

Basic UDI-DI:

404280940037793AC

Intended purpose:

Delta-Xpress™ Elbow is intended for short-term immobilization/stabilization of the elbow joint. The device is for single patient use.

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.

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Hamburg, 03.08.2023
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
72710-00000-03	DELTA-XPRESS COMFORT ELBOW SMALL WHITE 10 EN DE FR ES PT IT NL SV NO DA FI ZH AR	72710-00
72710-00001-03	DELTA-XPRESS COMFORT ELBOW MEDIUM WHITE 10 EN DE FR ES PT IT NL SV NO DA FI ZH AR	72710-01
72710-00002-03	DELTA-XPRESS COMFORT ELBOW LARGE WHITE 10 EN DE FR ES PT IT NL SV NO DA FI ZH AR	72710-02