

We,

**BSN medical Inc.  
5825 Carnegie Blvd.  
28209 Charlotte,  
USA  
(SRN: NOT ISSUED YET)**

hereby declare under our own responsibility, that this product family complies with the applicable regulations of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product Name:

**Delta-Solo® Cast Shoe**

Basic UDI-DI:

**4042809400418739C**

Intended purpose:

**Delta-Solo® Cast Shoe is intended to be used to protect casts and as a walking aid.**

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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Date of Issue: 19.10.2021

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Compiled and released:

Charlotte,, 19.10.2021  
Dr. Klaus-Steffen Nippe  
Glob. RA/PS Director, Medical Devices  
BSN medical Inc.

Article	Description	REF
72298-00012-01	DELTA-SOLO CAST SOLES EXTRA SMALL 10 CHILD	72298-12
72298-00013-01	DELTA-SOLO CAST SOLES SMALL 10	72298-13
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72298-00015-01	DELTA-SOLO CAST SOLES LARGE 10	72298-15
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72298-00040-02	DELTA-SOLO CAST SOLES WITH STRAPS EXTRA SMALL 10 CHILD	72298-40
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