

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: **ARTISTEP S**
Basic UDI-DI: **4042809400411157T**

Intended purpose: **Artistep S is intended to be worn over lower leg and foot casts providing a weight bearing surface while providing protection for the foot and cast from soiling.**

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:

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Date of Issue: 09.11.2020

**Dr. Andreas
Matthies**

Digitally signed by
Dr. Andreas Matthies
Date: 2020.11.09
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Compiled and released:

Charlotte,, 09.11.2020
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
45564-00000-05	ARTISTEP S PL(25-30) PEDIATRIC/LARGE BLUE 1 NL IT DE FR EN CAST BOOT	45564-00
45564-00001-01	ARTISTEP PEDIATRIC/MEDIUM BLUE 1 NL CAST SHOE (PM)	45564-01
45564-00002-01	ARTISTEP S PS(21-22) PEDIATRIC/SMALL BLUE 1 DA NL EN FI FR DE EL IT NO PT ES SV CAST BOOT	45564-02
45565-00000-05	ARTISTEP S EXTRA SMALL BLUE 1 NL IT FR EN DE GIPSSCHOEN	45565-00
45566-00000-05	ARTISTEP S SMALL BLUE 1 FR DE EN NL IT GIPSSCHOEN S	45566-00
45567-00000-05	ARTISTEP S MEDIUM BLUE 1 FR DE EN NL IT GIPSSCHOEN M	45567-00
45568-00000-05	ARTISTEP S LARGE BLUE 1 FR DE EN NL IT GIPSSCHOEN L	45568-00
45569-00000-05	ARTISTEP S EXTRA LARGE BLUE 1 FR DE EN NL IT GIPSSCHOEN XL	45569-00