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:	**ARTIFLEX**
Basic UDI-DI:	**4042809400422368F**
Intended purpose:	**ARTIFLEX is intended for padding purposes. Application fields include casting & splinting procedures, compression therapy and cushioning in prosthetics.**
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: NOT ISSUED YET)

Date of Issue: 15.03.2021

Dr. Andreas Matthies

Digitally signed by Dr. Andreas Matthies
Date: 2021.03.15 19:03:17 +01'00'

Compiled and released:

Charlotte,, 15.03.2021
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
09044-00000-06	ARTIFLEX 6CM X 3M 50	09044-00
09046-00000-06	ARTIFLEX 10CM X 3M 30	09046-00
09046-00009-02	ARTIFLEX 10CM X 3M WHITE 6 EN FR DE IT ES	09046-09
09047-00000-06	ARTIFLEX 15CM X 3M 20	09047-00
09048-00000-06	ARTIFLEX 20CM X 3M 15	09048-00