

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:

ARTIFLEX SOFT

Basic UDI-DI:

4042809400384809T

Intended purpose:

**Artiflex Soft 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
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(SRN: DE-AR-000005791)**

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Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
72860-00000-04	ARTIFLEX SOFT 6CM X 3MTR WHITE 50 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72860-00
72861-00000-04	ARTIFLEX SOFT 8CM X 3MTR WHITE 40 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72861-00
72862-00000-04	ARTIFLEX SOFT 10CM X 3MTR WHITE 30 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72862-00
72863-00000-04	ARTIFLEX SOFT 15CM X 3MTR WHITE 20 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72863-00
72864-00000-04	ARTIFLEX SOFT 20CM X 3MTR WHITE 15 AR ZH DA NL EN FI FR DE IT NO PT ES SV	72864-00