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:	**SOFFBAN SYNTHETIC**
Basic UDI-DI:	**404280940038486A7**
Intended purpose:	**Soffban® Synthetic 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
Quickbornstrasse 24
20253 Hamburg
Germany
(SRN: NOT ISSUED YET)

Date of Issue: 05/05/2020

Karla Worley-Ham

Digitally signed by Karla Worley-Ham
DN: cn=Karla Worley-Ham, o=BSN Medical Inc., an Essity Company, ou=Regulatory Affairs, email=karla.worley-ham@essity.com, c=US
Reason: I am approving this document
Date: 2020.05.05 11:04:33 -04'00'

Compiled and released:

Charlotte,, 05/05/2020
Karla Worley-Ham
Director Regulatory Affairs, LM NA
BSN medical Inc.

Article	Description	REF
71464-00001-03	SOFFBAN SYNTHETIC PADDING 5CM X 2.7M 12 AR ZH CS DA NL EN FI FR DE IT NO PT ES SV	71464-01
71465-00001-03	SOFFBAN SYNTHETIC PADDING 15CM X 2.7M 12 AR ZH CS DA NL EN FI FR DE IT NO PT ES SV	71465-01
71466-00001-03	SOFFBAN SYNTHETIC PADDING 20CM X 2.7M 6 AR ZH CS DA NL EN FI FR DE IT NO PT ES SV	71466-01
71467-00001-03	SOFFBAN SYNTHETIC PADDING 7.5CM X 2.7M 12 AR ZH CS DA NL EN FI FR DE IT NO PT ES SV	71467-01
71486-00005-03	SOFFBAN SYNTHETIC PADDING 10CM X 2.7M 12 AR ZH CS DA NL EN FI FR DE IT NO PT ES SV	71486-05