

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 NATURAL**
Basic UDI-DI: **404280940038807A5**

Intended purpose: **Soffban® Natural 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:

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(SRN: NOT ISSUED YET)**

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Charlotte,, 05/05/2020
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BSN medical Inc.

Article	Description	REF
71469-00000-03	SOFFBAN NATURAL PAD 10CM X 2.7M WHITE 12 AR ZH DA NL EN FI FR DE IT NO PT ES SV	71469-00
71470-00000-03	SOFFBAN NATURAL PAD 15CM X 2.7M WHITE 12 AR ZH DA NL EN FI FR DE IT NO PT ES SV	71470-00
71471-00000-03	SOFFBAN NATURAL PAD 20CM X 2.7M WHITE 6 AR ZH DA NL EN FI FR DE IT NO PT ES SV	71471-00
71472-00000-03	SOFFBAN NATURAL PAD 5CM X 2.7M WHITE 12 AR ZH DA NL EN FI FR DE IT NO PT ES SV	71472-00
71473-00000-03	SOFFBAN NATURAL PAD 7.5CM X 2.7M WHITE 12 AR ZH DA NL EN FI FR DE IT NO PT ES SV	71473-00