

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:

Krepppapierbinde-BSN

Basic UDI-DI:

4042809400422268C

Intended purpose:

Krepppapierbinde-BSN (Crepe paper bandage) is intended for compression and retention of undercast padding materials. When used in combination with Plaster of Paris, it helps preventing water entering the padding layers.

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: DE-AR-000005791)**

Date of Issue: 13.10.2023

Andreas Matthies

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Compiled and released:

Charlotte,, 13.10.2023
Dr. Andreas Matthies
Global Regulatory Affairs Director
BSN medical Inc.

Article	Description	REF
01790-00000-05	BMP IDEAL CREPE 4M X 4CM 1 DE KREPPAPIER	01790-00
01791-00000-05	BMP IDEAL CREPE 4M X 6CM 1 DE KREPPBINDE	01791-00
01792-00000-05	BMP IDEAL CREPE 4M X 8CM 1 DE KREPPBINDE	01792-00
01793-00000-05	BMP IDEAL CREPE 4M X 10CM 1 DE KREPPBINDE	01793-00
01794-00000-05	BMP IDEAL CREPE 4M X 12CM 1 DE KREPPBINDE	01794-00