

We,

**BSN medical GmbH
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20253 Hamburg
Germany
(SRN: DE-MF-000005787)**

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:

Cutisoft®

Basic UDI-DI:

4042809400396039S

Intended purpose:

Cutisoft® is intended for skin and wound cleansing, absorption of secretion/exudates and is suitable as a primary or secondary dressing. The device is for short-term use. The use of device is not restricted to a specific patient population.

Conformity assessment route: **Annex II+III**

Classification rule:

4

Classification:

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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.

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Compiled and released:

Hamburg, 04.08.2020
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
45838-00000-02	CUTISOFT NON STERILE 10X20CM 100 IT NL EN DE	45838-00
45844-00000-05	CUTISOFT NON STERILE 5X5CM 100 IT NL EN DE	45844-00
45845-00000-05	CUTISOFT NON STERILE 7,5X7,5CM 100 IT NL EN DE	45845-00
45846-00000-05	CUTISOFT NON STERILE 10X10CM 100 NL IT EN DE	45846-00