

We,

**BSN medical GmbH
Schützenstr. 1-3
22761 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:

Cutimed® Cavity

Basic UDI-DI:

4042809400434889K

Intended purpose:

Cutimed® Cavity is indicated for the management of chronic and acute deep wounds with moderate to high exudate levels, such as pressure ulcers, deep leg ulcers, cavity wounds, diabetic ulcers, trauma wounds, and post-operative wounds.

Conformity assessment route: **Annex IX, Chapter I**

Classification rule:

4

Classification:

IIb

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.

This declaration is only valid in conjunction with the current E.C. certificates issued by DEKRA Certification GmbH (Id. No. 0124), Handwerkstraße 15, 70565 Stuttgart, Germany.

Number of E.C. certificate: 50708-60-04

Declaration of conformity issued: 27.03.2024

Compiled and released:

Hamburg, 27.03.2024
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
72621-00000-04	CUTIMED CAVITY STERILE 5X6CM 10 DA NL EN FI FR DE NO ES SV	72621-00
72621-00001-04	CUTIMED CAVITY STERILE 10X10CM 10 DA NL EN FI FR DE NO ES SV	72621-01
72621-00003-04	CUTIMED CAVITY STERILE 15X15CM 5 DA NL EN FI FR DE NO ES SV	72621-03