

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® Gel

Basic UDI-DI:

404280940049078A6

Intended purpose:

Cutimed® Gel produces a moist, physiological wound environment and supports autolytic cleansing of necrotic or unclean wounds (e.g. lightly weeping ulcer cruris, diabetic foot syndrome, decubital ulcers or first and second-degree burns).

Conformity assessment route: **Annex IX, Chapter I+III**
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: 50708-60-05

Declaration of conformity issued: 22.11.2024

Compiled and released:

Hamburg, 22.11.2024
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
72610-00000-04	CUTIMED GEL STERILE 8G 10 DE EN FR ES	72610-00
72610-00001-04	CUTIMED GEL STERILE 15G 10 EN FR DE ES	72610-01
72610-00002-04	CUTIMED GEL STERILE 25G TRANSPARENT 10 DE EN FR ES	72610-02