

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® Cuticell®

Basic UDI-DI:

4042809400462699S

Intended purpose:

Cutimed® Cuticell® is a primary wound contact layer indicated for the treatment of superficial exudating wounds such as:
• **Superficial and partial thickness burns**
• **Donor and recipient skin graft sites**
• **Lacerations and abrasions**
• **Radiation injuries**

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: 50708-60-05

Declaration of conformity issued: 29.07.2024

Compiled and released:

Hamburg, 29.07.2024
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
71007-00000-00	CUTIMED CUTICELL STERILE 7.5CMX7.5CM 10 DA NL EN FI FR DE IT NO PT ES SV	71007-00
71007-00001-00	CUTIMED CUTICELL STERILE 7.5CMX7.5CM 50 DA NL EN FI FR DE IT NO PT ES SV	71007-01
71007-00002-00	CUTIMED CUTICELL STERILE 7.5CMX20CM 10 DA NL EN FI FR DE IT NO PT ES SV	71007-02
71007-00003-00	CUTIMED CUTICELL STERILE 7.5CMX20CM 50 DA NL EN FI FR DE IT NO PT ES SV	71007-03
71007-00004-00	CUTIMED CUTICELL STERILE 20CMX40CM 25 DA NL EN FI FR DE IT NO PT ES SV	71007-04