

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® Gelling Fiber

Basic UDI-DI:

4042809400368109C

Intended purpose:

**Cutimed® Gelling Fiber is intended for the treatment of moderately to highly exuding wounds healing by secondary intention, such as: leg ulcers, pressure ulcers (stage II-IV) and diabetic ulcers surgical wounds (e.g., post-operative, wounds left to heal by secondary intent and donor sites), partial thickness burns, exudate absorption in oncology wounds, traumatic wounds (e.g., abrasions and lacerations).
The dressing can be used for dry wounds, but care should be taken when removing the dressing. Cutimed® Gelling Fiber can be used under compression.**

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: 24.09.2024

Compiled and released:

Hamburg, 24.09.2024
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
71218-00000-02	CUTIMED GELLING FIBER STERILE 5X5CM 10 AR DA NL EN FI FR DE IT NO PT ES SV	71218-00
71218-00001-02	CUTIMED GELLING FIBER STERILE 10X10CM 10 AR DA NL EN FI FR DE IT NO PT ES SV	71218-01
71218-00002-02	CUTIMED GELLING FIBER STERILE 15X15CM 5 AR DA NL EN FI FR DE IT NO PT ES SV	71218-02
71218-00003-02	CUTIMED GELLING FIBER STERILE 4X10CM 10 AR DA NL EN FI FR DE IT NO PT ES SV	71218-03
71218-00004-02	CUTIMED GELLING FIBER STERILE 4X20CM 10 AR DA NL EN FI FR DE IT NO PT ES SV	71218-04
71218-00005-02	CUTIMED GELLING FIBER STERILE 4X30CM 10 AR DA NL EN FI FR DE IT NO PT ES SV	71218-05
71218-00006-02	CUTIMED GELLING FIBER STERILE 2X45CM 5 AR DA NL EN FI FR DE IT NO PT ES SV	71218-06
71218-00007-02	CUTIMED GELLING FIBER STERILE 1X45CM 5 AR DA NL EN FI FR DE IT NO PT ES SV	71218-07
71218-00008-02	CUTIMED GELLING FIBER STERILE 10X10CM 3 DE (71218-01-00) SAMPLE NOT FOR SELLING	71218-08