

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® DeбриClean

Basic UDI-DI:

4042809400407999J

Intended purpose:

Cutimed® DeбриClean is intended for the debridement of superficial wounds and surrounding skin in, for example diabetic ulcers, venous and arterial ulcers, pressure sores, postoperative wounds and wounds healing by secondary intention, superficial burns, the absorption of exudate, slough and dry skin flakes.

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.

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BSN medical GmbH

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