

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® PROTECT

Basic UDI-DI:

404280940039625A4

Intended purpose:

Cutimed® PROTECT Foam Applicator is supplied as a liquid and intended for use as a film-forming product. When applied to intact or irritated skin the product forms a durable, waterproof barrier that works as a protective shield between the skin and bodily waste, fluids, adhesive products and shearing forces. The product is designed to serve as a primary barrier against irritation from bodily fluids.

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

Classification rule:

4

Classification:

Is

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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Hamburg, 11.08.2023
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
72654-00000-03	CUTIMED PROTECT FOAM STERILE 1ML 5 NL EN FR DE IT PT ES	72654-00
72654-00001-03	CUTIMED PROTECT FOAM STERILE 1ML 25 NL EN FR DE IT PT ES	72654-01
72654-00002-05	CUTIMED PROTECT FOAM STERILE 3ML 5 NL EN FR DE IT PT ES	72654-02
72654-00003-05	CUTIMED PROTECT FOAM STERILE 3ML 25 NL EN FR DE IT PT ES	72654-03