

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:

**4042809400396309V**

Intended purpose:

**Cutimed® PROTECT Spray 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 II+III**  
Classification rule: **4**  
Classification: **I**

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.

Declaration of conformity issued: 14.02.2025

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Compiled and released:

Hamburg, 14.02.2025  
Martin Spengler  
Director Regulatory Affairs Hamburg  
BSN medical GmbH



Article	Description	REF
72653-00000-03	CUTIMED PROTECT SPRAY 28ML 1 NL EN FR DE IT ES	72653-00
72653-00001-03	CUTIMED PROTECT SPRAY 28ML 12 NL EN FR DE IT ES	72653-01