

## **Declaration of Conformity Cutimed® PROTECT**

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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: 404280940039633A3

Intended purpose:

Cutimed® PROTECT Cream protects skin from damage and irritation, particularly at-risk areas associated with incontinence. Cutimed® PROTECT Cream safeguards skin from damage associated with chronic incontinence. It

moisturises and protects dry skin.

Conformity assessment route: Annex II+III

Classification rule: Classification:

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: 13.09.2024

Compiled and released:

Hamburg, 13.09.2024 Dr. Thomas Mehler Global Quality Director Medical BSN medical GmbH

Digitally signed by Thomas.Mehler DN: cn=Thomas.Mehler Date: 2024.09.13

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Article	Description	REF
72652-00000-04	CUTIMED PROTECT CREAM 28G 1 NL EN FR DE IT PT ES	72652-00
72652-00003-04	CUTIMED PROTECT CREAM 90G 12 NL EN FR DE IT PT ES	72652-03