

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® Siltec®

Basic UDI-DI:

40428094004348399

Intended purpose:

**Cutimed® Siltec® foam dressings are indicated for the treatment of exuding wounds with low to high exudate levels such as venous and arterial ulcers, pressure ulcers, diabetic foot ulcers, surgical incisions, skin grafts and donor sites, lacerations or abrasions.
Cutimed® Siltec® foam dressings may assist in the prevention of pressure ulcer as part of a comprehensive plan of continuous care, risk assessment and preventive care by a healthcare facility and healthcare professional.**

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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Dr. Thomas Mehler
Global Quality Director Medical
BSN medical GmbH



Article	Description	REF
71222-00000-00	LEUKOPLAST CUTIMED SILTEC STERILE 10X10CM 2 DA NL EN FI FR DE IT NO PT ES SV	71222-00
73285-00000-01	CUTIMED SILTEC STERILE 5X6CM 10 DA NL EN FI FR DE IT NO ES SV	73285-00
73285-00001-01	CUTIMED SILTEC STERILE 10X10CM 10 DA NL EN FI FR DE IT NO ES SV	73285-01
73285-00002-01	CUTIMED SILTEC STERILE 10X20CM 10 DA NL EN FI FR DE IT NO ES SV	73285-02
73285-00003-01	CUTIMED SILTEC STERILE 15X15CM 10 DA NL EN FI FR DE IT NO ES SV	73285-03
73285-00004-01	CUTIMED SILTEC STERILE 20X20CM 5 DA NL EN FI FR DE IT NO ES SV	73285-04
73285-00005-01	CUTIMED SILTEC STERILE 5X6CM 12 DE	73285-05
73285-00006-01	CUTIMED SILTEC STERILE 10X10CM 12 DE	73285-06
73285-00007-01	CUTIMED SILTEC STERILE 10X20CM 12 DE	73285-07
73285-00008-01	CUTIMED SILTEC STERILE 15X15CM 12 DE	73285-08
73285-00009-01	CUTIMED SILTEC STERILE 20X20CM 6 DE	73285-09