

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® PLUS

Basic UDI-DI:

4042809400434869F

Intended purpose:

**Cutimed® Siltec® PLUS 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® PLUS 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
73288-00000-02	CUTIMED SILTEC PLUS STERILE 5X6CM 10 DE DA EN FI FR IT NL NO SV ES	73288-00
73288-00001-02	CUTIMED SILTEC PLUS STERILE 10X10CM 10 DE DA EN FI FR IT NL NO SV ES	73288-01
73288-00002-02	CUTIMED SILTEC PLUS STERILE 10X20CM 10 DE DA EN FI FR IT NL NO SV ES	73288-02
73288-00003-02	CUTIMED SILTEC PLUS STERILE 15X15CM 10 DE DA EN FI FR IT NL NO SV ES	73288-03
73288-00004-02	CUTIMED SILTEC PLUS STERILE 20X20CM 5 DE DA EN FI FR IT NL NO SV ES	73288-04
73288-00006-02	CUTIMED SILTEC PLUS STERILE 5X6CM 12 DE	73288-06
73288-00007-02	CUTIMED SILTEC PLUS STERILE 10X10CM 12 DE	73288-07
73288-00008-02	CUTIMED SILTEC PLUS STERILE 10X20CM 12 DE	73288-08
73288-00009-02	CUTIMED SILTEC PLUS STERILE 15X15CM 12 DE	73288-09
73288-00010-02	CUTIMED SILTEC PLUS STERILE 20X20CM 6 DE	73288-10
73288-00011-02	CUTIMED SILTEC PLUS 10X10 10 FR LPPR 73288-01	73288-11
73288-00012-02	CUTIMED SILTEC PLUS 10X20 10 FR LPPR 73288-02	73288-12
73288-00013-02	CUTIMED SILTEC PLUS 15X15 10 FR LPPR 73288-03	73288-13
73288-00015-00	CUTIMED SILTEC PLUS STERILE 10X10CM 3 DE (73288-07-01) SAMPLE NOT FOR SELLING	73288-15