

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® B / Cutimed® Siltec® Sacrum

Basic UDI-DI:

4042809400407908Y

Intended purpose:

Cutimed® Siltec® B and Cutimed® Siltec® Sacrum are intended 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® B and Cutimed® Siltec® Sacrum 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.

Date of Issue: 04.02.2022



Compiled and released:

Hamburg, 04.02.2022
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH

Article	Description	REF
71221-00000-00	LEUKOPLAST CUTIMED SILTEC B STERILE 7.5X7.5CM 3 DA NL EN FI FR DE IT NO ES SV	71221-00
71221-00001-00	LEUKOPLAST CUTIMED SILTEC B STERILE 10X10CM 2 DA NL EN FI FR DE IT NO ES SV	71221-01
73284-00000-01	CUTIMED SILTEC B STERILE 7.5X7.5CM 10 DA NL EN FI FR DE IT NO ES SV	73284-00
73284-00001-01	CUTIMED SILTEC B STERILE 12.5X12.5CM 10 DA NL EN FI FR DE IT NO ES SV	73284-01
73284-00002-01	CUTIMED SILTEC B STERILE 15X15CM 10 DA NL EN FI FR DE IT NO ES SV	73284-02
73284-00003-01	CUTIMED SILTEC B STERILE 17.5X17.5CM 5 DA NL EN FI FR DE IT NO ES SV	73284-03
73284-00004-01	CUTIMED SILTEC B STERILE 22.5X22.5CM 5 DA NL EN FI FR DE IT NO ES SV	73284-04
73284-00005-01	CUTIMED SILTEC B STERILE 10X10CM 10 DE DA EN FI FR IT NL NO SV ES	73284-05
73284-00006-01	CUTIMED SILTEC B STERILE 10X22.5CM 10 DE DA EN FI FR IT NL NO SV ES	73284-06
73284-00007-01	CUTIMED SILTEC B STERILE 7.5X7.5CM 12 DE	73284-07
73284-00008-01	CUTIMED SILTEC B STERILE 12.5X12.5CM 12 DE	73284-08
73284-00009-01	CUTIMED SILTEC B STERILE 15X15CM 12 DE	73284-09
73284-00010-01	CUTIMED SILTEC B STERILE 17.5X17.5CM 6 DE	73284-10
73284-00011-01	CUTIMED SILTEC B STERILE 22.5X22.5CM 6 DE	73284-11
73284-00012-01	CUTIMED SILTEC B STERILE 10X10CM 12 DE	73284-12
73284-00013-01	CUTIMED SILTEC B STERILE 10X22.5CM 12 DE	73284-13
73284-00014-01	CUTIMED SILTEC B STERILE 7X10CM OVALE 10 DE DA EN FI FR IT NL NO SV ES	73284-14
73284-00015-01	CUTIMED SILTEC B STERILE 7X10CM OVALE 12 DE	73284-15
73284-00016-01	CUTIMED SILTEC B 12.5X12.5 10 FR LPPR 73284-01	73284-16
73284-00017-01	CUTIMED SILTEC B STERILE 15X15 10 FR LPPR 73284-02	73284-17

Article	Description	REF
73284-00018-01	CUTIMED SILTEC B STERILE 10X10 10 FR LPPR 73284-05	73284-18
73284-00019-01	CUTIMED SILTEC B 10X22.5 10 FR LPPR 73284-06	73284-19
73284-00020-01	CUTIMED SILTEC B STERILE 7X10 10 FR LPPR 73284-14	73284-20
73284-00021-01	CUTIMED SILTEC B STERILE 13X16CM OVALE 5 DE DA EN FI FR IT NL NO SV ES	73284-21
73284-00022-01	CUTIMED SILTEC B STERILE 13X16CM OVALE 6 DE	73284-22
73284-00034-00	CUTIMED SILTEC B STERILE 13X16CM OVALE 3 DE (73284-22-00) SAMPLE NOT FOR SELLING	73284-34
73284-00035-00	CUTIMED SILTEC B STERILE 10X10CM 3 DE (73284-12-00) SAMPLE NOT FOR SELLING	73284-35
73287-00000-01	CUTIMED SILTEC SACRUM STERILE 17.5X17.5CM 5 DE NL EN FR IT ES	73287-00
73287-00001-01	CUTIMED SILTEC SACRUM STERILE 23X23CM 5 DE NL EN FR IT ES	73287-01
73287-00002-01	CUTIMED SILTEC SACRUM STERILE 17.5X17.5CM 6 DE	73287-02
73287-00003-01	CUTIMED SILTEC SACRUM STERILE 23X23CM 6 DE	73287-03
73287-00004-01	CUTIMED SILTEC SACRUM 17.5X17.5 5 FR LPPR 73287-00	73287-04
73287-00005-01	CUTIMED SILTEC SACRUM STERILE 23X23 5 FR LPPR 73287-01	73287-05