

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® Sorbion® Border

Basic UDI-DI:

4042809400368059K

Intended purpose:

Cutimed® Sorbion® Border is intended for the treatment of exuding wounds with moderate to excessive levels healing by secondary intention such as decubitus, ulcus cruris, diabetic foot ulcer and other wounds healing through secondary intention, oozing laparotomy wounds, fistulas to the skin, exulcerating carcinomas, postoperative wound dehiscence and similar exuding wounds.

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: 12.10.2022

Compiled and released:

Hamburg, 12.10.2022
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
71010-00000-01	CUTIMED SORBION BORDER STERILE 10X10CM 10 DA NL EN FI FR DE IT NO PT ES SV	71010-00
71010-00002-01	CUTIMED SORBION BORDER STERILE 15X15CM 10 DE EN FR ES IT NL PT SV DA NO FI	71010-02
71010-00003-01	CUTIMED SORBION BORDER STERILE 20X20CM 10 DE EN FR ES IT NL PT SV DA NO FI	71010-03
71010-00004-01	CUTIMED SORBION BORDER STERILE 10X23CM 10 DE EN FR ES IT NL PT SV DA NO FI	71010-04
71010-00007-01	CUTIMED SORBION BORDER STERILE 9X11CM 10 DE EN FR ES IT NL PT SV DA NO FI OVAL	71010-07
71010-00008-01	CUTIMED SORBION BORDER SACRUM STERILE 19.5X22CM 10 DE EN FR ES IT NL PT SV DA NO FI	71010-08
71010-00009-00	CUTIMED SORBION BORDER STERILE 10X10CM 12 DE	71010-09
71010-00010-00	CUTIMED SORBION BORDER STERILE 15X15CM 12 DE	71010-10
71010-00011-00	CUTIMED SORBION BORDER STERILE 20X20CM 12 DE	71010-11
71010-00012-00	CUTIMED SORBION BORDER STERILE 10X23CM 12 DE	71010-12
71010-00015-01	CUTIMED SORBION BORDER 10X10 FR LPPR71010-0-1	71010-15
71010-00016-01	CUTIMED SORBION BORDER 15X15 10 LPPR71010-2-1	71010-16
71010-00017-01	CUTIMED SORBION BORDER 20X20 10 LPPR71010-3-1	71010-17
71010-00018-01	CUTIMED SORBION BORDER 10X23 10 LPPR71010-4-1	71010-18
71010-00019-01	CUTIMED SORBION BORDER 9X11 10 LPPR 71010-7-1 OVAL	71010-19
71010-00020-01	CUTIMED SORBION BORDER 19,5X22 10 71010-8-1 LPPR SACRUM	71010-20

Article	Description	REF
71010-00022-00	CUTIMED SORBION BORDER STERILE 15X15CM 3 DE (71010-10-00) SAMPLE NOT FOR SELLING	71010-22