

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® Sachet Extra / Cutimed® Sorbion® Sachet Multi Star / Cutimed® Sorbion® Sachet S / Cutimed® Sorbion® Sachet S Drainage / Cutimed® Sorbion® Sachet XL

Basic UDI-DI:

4042809400490229B

Intended purpose:

Cutimed® Sorbion® Sachet is intended for the treatment of wounds with moderate to excessive exudate levels such as decubitus, ulcus cruris, diabetic foot ulcers and other wounds healing through secondary intention, oozing laparotomy wounds, fistulas to the skin, exulcerating carcinomas, postoperative wound dehiscence and similar exuding wounds. Note: Cutimed® Sorbion® Sachet S Drainage, due to its specific shape, was developed for use with catheters, drainages, etc.

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.

Number of E.C. certificate: 50708-60-04

Declaration of conformity issued: 28.03.2024

Compiled and released:

Hamburg, 28.03.2024
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
73232-00000-06	CUTIMED SORBION SACHET S STERILE 7.5X7.5CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73232-00
73232-00001-06	CUTIMED SORBION SACHET S STERILE 7.5X7.5CM WHITE 25 EN FR DE NL IT ES PT SV FI NO DA AR	73232-01
73232-00002-06	CUTIMED SORBION SACHET S STERILE 7.5X7.5CM WHITE 50 EN FR DE NL IT ES PT SV FI NO DA AR	73232-02
73232-00003-06	CUTIMED SORBION SACHET S STERILE 5X12CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73232-03
73232-00004-06	CUTIMED SORBION SACHET S STERILE 5X12CM WHITE 25 EN FR DE NL IT ES PT SV FI NO DA AR	73232-04
73232-00005-06	CUTIMED SORBION SACHET S STERILE 5X12CM WHITE 50 EN FR DE NL IT ES PT SV FI NO DA AR	73232-05
73232-00006-06	CUTIMED SORBION SACHET S STERILE 10X10CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73232-06
73232-00007-06	CUTIMED SORBION SACHET S STERILE 10X10CM WHITE 25 EN FR DE NL IT ES PT SV FI NO DA AR	73232-07
73232-00008-06	CUTIMED SORBION SACHET S STERILE 10X10CM WHITE 50 EN FR DE NL IT ES PT SV FI NO DA AR	73232-08
73232-00009-06	CUTIMED SORBION SACHET S STERILE 10X20CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73232-09
73232-00010-06	CUTIMED SORBION SACHET S STERILE 10X20CM WHITE 25 EN FR DE NL IT ES PT SV FI NO DA AR	73232-10
73232-00011-06	CUTIMED SORBION SACHET S STERILE 10X20CM WHITE 50 EN FR DE NL IT ES PT SV FI NO DA AR	73232-11
73232-00012-06	CUTIMED SORBION SACHET S STERILE 15X15CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73232-12

Article	Description	REF
73232-00013-06	CUTIMED SORBION SACHET S STERILE 15X15CM WHITE 25 EN FR DE NL IT ES PT SV FI NO DA AR	73232-13
73232-00014-06	CUTIMED SORBION SACHET S STERILE 15X15CM WHITE 50 EN FR DE NL IT ES PT SV FI NO DA AR	73232-14
73232-00015-06	CUTIMED SORBION SACHET S STERILE 20X20CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73232-15
73232-00016-06	CUTIMED SORBION SACHET S STERILE 20X20CM WHITE 25 EN FR DE NL IT ES PT SV FI NO DA AR	73232-16
73232-00017-06	CUTIMED SORBION SACHET S STERILE 20X20CM WHITE 50 EN FR DE NL IT ES PT SV FI NO DA AR	73232-17
73232-00018-06	CUTIMED SORBION SACHET S STERILE 20X30CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73232-18
73232-00019-06	CUTIMED SORBION SACHET S STERILE 20X30CM WHITE 25 EN FR DE NL IT ES PT SV FI NO DA AR	73232-19
73232-00020-06	CUTIMED SORBION SACHET S STERILE 20X30CM WHITE 50 EN FR DE NL IT ES PT SV FI NO DA AR	73232-20
73232-00021-06	CUTIMED SORBION SACHET S STERILE 10X18CM WHITE 25 EN FR DE NL IT ES PT SV FI NO DA AR	73232-21
73232-00022-06	CUTIMED SORBION SACHET S STERILE 10X18CM WHITE 50 EN FR DE NL IT ES PT SV FI NO DA AR	73232-22
73232-00040-06	CUTIMED SORBION SACHET S STERILE 7.5X7.5CM WHITE 12 DE	73232-40
73232-00041-06	CUTIMED SORBION SACHET S STERILE 7.5X7.5CM WHITE 24 DE	73232-41
73232-00042-06	CUTIMED SORBION SACHET S STERILE 7.5X7.5CM WHITE 48 DE	73232-42
73232-00043-06	CUTIMED SORBION SACHET S STERILE 5X12CM WHITE 12 DE	73232-43
73232-00044-06	CUTIMED SORBION SACHET S STERILE	73232-44

Article	Description	REF
	10X10CM WHITE 12 DE	
73232-00045-06	CUTIMED SORBION SACHET S STERILE 10X10CM WHITE 24 DE	73232-45
73232-00046-06	CUTIMED SORBION SACHET S STERILE 10X10CM WHITE 48 DE	73232-46
73232-00047-06	CUTIMED SORBION SACHET S STERILE 10X20CM WHITE 12 DE	73232-47
73232-00048-06	CUTIMED SORBION SACHET S STERILE 10X20CM WHITE 24 DE	73232-48
73232-00049-06	CUTIMED SORBION SACHET S STERILE 10X20CM WHITE 48 DE	73232-49
73232-00050-06	CUTIMED SORBION SACHET S STERILE 15X15CM WHITE 12 DE	73232-50
73232-00051-06	CUTIMED SORBION SACHET S STERILE 15X15CM WHITE 24 DE	73232-51
73232-00052-06	CUTIMED SORBION SACHET S STERILE 20X20CM WHITE 12 DE	73232-52
73232-00053-06	CUTIMED SORBION SACHET S STERILE 20X20CM WHITE 24 DE	73232-53
73232-00054-06	CUTIMED SORBION SACHET S STERILE 20X20CM WHITE 48 DE	73232-54
73232-00055-06	CUTIMED SORBION SACHET S STERILE 20X30CM WHITE 12 DE	73232-55
73232-00056-06	CUTIMED SORBION SACHET S STERILE 20X30CM WHITE 24 DE	73232-56
73232-00057-06	CUTIMED SORBION SACHET S STERILE 20X30CM WHITE 48 DE	73232-57
73232-00058-06	CUTIMED SORBION SACHET S 7.5X7.5 10 LPPR73232-00-06	73232-58
73232-00059-06	CUTIMED SORBION SACHET S STE5X12 10 LPPR73232-03-06	73232-59
73232-00060-06	CUTIMED SORBION SACHET S STE10X10 10 LPPR73232-06-06	73232-60
73232-00061-06	CUTIMED SORBION SACHET S STE10X20 10 LPPR73232-09-06	73232-61
73232-00062-06	CUTIMED SORBION SACHET S STE15X15 10 LPPR73232-12-06	73232-62

Article	Description	REF
73232-00063-06	CUTIMED SORBION SACHET S 20X20 10 LPPR73232-15-06	73232-63
73232-00064-06	CUTIMED SORBION SACHET S 20X30 10 LPPR73232-18-06	73232-64
73232-00065-06	CUTIMED SORBION SACHET S STERILE 10X10CM WHITE 3 DE (73232-00044-06) SAMPLE NOT FOR SELLING	73232-65
73232-00066-06	CUTIMED SORBION SACHET S STERILE 10X20CM WHITE 3 DE (73232-00047-06) SAMPLE NOT FOR SELLING	73232-66
73232-00067-06	CUTIMED SORBION SACHET S STERILE 20X20CM WHITE 3 DE (73232-00052-06) SAMPLE NOT FOR SELLING	73232-67
73232-00068-06	CUTIMED SORBION SACHET S STERILE 12.5X12.5CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73232-68
73232-00069-06	CUTIMED SORBION SACHET S STERILE 15X20CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73232-69
73234-00000-06	CUTIMED SORBION SACHET EXTRA STERILE 5X5CM WHITE 5 EN FR DE NL IT ES PT SV FI NO DA AR	73234-00
73234-00001-06	CUTIMED SORBION SACHET EXTRA STERILE 7.5X7.5CM WHITE 5 EN FR DE NL IT ES PT SV FI NO DA AR	73234-01
73234-00002-06	CUTIMED SORBION SACHET EXTRA STERILE 10X10CM WHITE 5 EN FR DE NL IT ES PT SV FI NO DA AR	73234-02
73234-00003-06	CUTIMED SORBION SACHET EXTRA STERILE 10X20CM WHITE 5 EN FR DE NL IT ES PT SV FI NO DA AR	73234-03
73234-00004-06	CUTIMED SORBION SACHET EXTRA STERILE 20X20CM WHITE 5 EN FR DE NL IT ES PT SV FI NO DA AR	73234-04
73234-00005-06	CUTIMED SORBION SACHET EXTRA STERILE 20X30CM WHITE 5 EN FR DE NL IT ES PT SV FI NO DA AR	73234-05
73237-00000-06	CUTIMED SORBION SACHET MULTI STAR STERILE D 8CM WHITE 5 EN FR DE NL IT ES	73237-00

Article	Description	REF
	PT SV FI NO DA AR	
73237-00001-06	CUTIMED SORBION SACHET MULTI STAR STERILE D 8CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73237-01
73237-00002-06	CUTIMED SORBION SACHET MULTI STAR STERILE D 14CM WHITE 5 EN FR DE NL IT ES PT SV FI NO DA AR	73237-02
73237-00003-06	CUTIMED SORBION SACHET MULTI STAR STERILE D 14CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73237-03
73237-00006-06	CUTIMED SORBION SACHET MULTI STAR D8 10 LPPR73237-01-06	73237-06
73237-00007-06	CUTIMED SORBION SACHET MULTI STAR D14 10 LPPR73237-03-06	73237-07
73237-00008-06	CUTIMED SORBION SACHET MULTI STAR STERILE D 8CM WHITE 3 DE (73237-00001-06) SAMPLE NOT FOR SELLING	73237-08
73240-00000-06	CUTIMED SORBION SACHET XL STERILE 25X45CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73240-00
73240-00001-06	CUTIMED SORBION SACHET XL STERILE 25X45CM WHITE 5 EN FR DE NL IT ES PT SV FI NO DA AR	73240-01
73240-00003-06	CUTIMED SORBION SACHET XL STERILE 25X45CM WHITE 12 DE	73240-03
73240-00004-06	CUTIMED SORBION SACHET XL STERILE 25X45CM WHITE 6 DE	73240-04
73240-00005-06	CUTIMED SORBION SACHET XL 25X45 10 LPPR73240-00-06	73240-05
73240-00006-06	CUTIMED SORBION SACHET XL STERILE 25X45CM WHITE 2 DE (73240-00004-06) SAMPLE NOT FOR SELLING	73240-06
73241-00000-06	CUTIMED SORBION SACHET DRAIN STERILE 10X10CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73241-00
73241-00001-06	CUTIMED SORBION SACHET DRAIN STERILE 10X10CM WHITE 25 EN FR DE NL IT ES PT SV FI NO DA AR	73241-01
73241-00002-06	CUTIMED SORBION SACHET DRAIN STERILE	73241-02

Article	Description	REF
	10X10CM WHITE 50 EN FR DE NL IT ES PT SV FI NO DA AR	
73241-00004-06	CUTIMED SORBION SACHET DRAIN STERILE 10X10CM WHITE 3 DE (73241-00001-06) SAMPLE NOT FOR SELLING	73241-04
73241-00005-06	CUTIMED SORBION 10X10CM 10 LPPR73241-00-06 SACHET DRAIN STERILE	73241-05