

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® Sana, Cutimed® Sorbion® Sana XL,
Cutimed® Sorbion® Sana Multi Star**

Basic UDI-DI:

4042809400490399U

Intended purpose:

Cutimed® Sorbion® Sana is intended for the treatment of wounds with low to excessive exudate levels, such as decubitus ulcers, ulcus cruris, diabetic foot ulcers and other wounds healing through secondary intention, dehisced wounds, as well as after burns, on donor sites and fragile skin, epidermolysis bullosa (EB) and hidradenitis suppurativa (HS).

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: 08.04.2024

Compiled and released:

Hamburg, 08.04.2024
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
73233-00000-06	CUTIMED SORBION SANA STERILE 8.5X8.5CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73233-00
73233-00003-06	CUTIMED SORBION SANA STERILE 12X12CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73233-03
73233-00006-06	CUTIMED SORBION SANA STERILE 12X22CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73233-06
73233-00007-06	CUTIMED SORBION SANA STERILE 12X22CM WHITE 25 EN FR DE NL IT ES PT SV FI NO DA AR	73233-07
73233-00009-06	CUTIMED SORBION SANA STERILE 22X22CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73233-09
73233-00030-06	CUTIMED SORBION SANA STERILE 8.5X8.5CM WHITE 12 DE	73233-30
73233-00031-06	CUTIMED SORBION SANA STERILE 8.5X8.5CM WHITE 24 DE	73233-31
73233-00032-06	CUTIMED SORBION SANA STERILE 8.5X8.5CM WHITE 48 DE	73233-32
73233-00033-06	CUTIMED SORBION SANA STERILE 12X12CM WHITE 12 DE	73233-33
73233-00034-06	CUTIMED SORBION SANA STERILE 12X12CM WHITE 24 DE	73233-34
73233-00035-06	CUTIMED SORBION SANA STERILE 12X12CM WHITE 48 DE	73233-35
73233-00036-06	CUTIMED SORBION SANA STERILE 12X22CM WHITE 12 DE	73233-36
73233-00037-06	CUTIMED SORBION SANA STERILE 12X22CM WHITE 24 DE	73233-37
73233-00038-06	CUTIMED SORBION SANA STERILE 12X22CM WHITE 48 DE	73233-38
73233-00039-06	CUTIMED SORBION SANA STERILE 22X22CM WHITE 12 DE	73233-39
73233-00040-06	CUTIMED SORBION SANA STERILE 22X22CM WHITE 24 DE	73233-40
73233-00041-06	CUTIMED SORBION SANA STERILE 22X22CM	73233-41

Article	Description	REF
	WHITE 48 DE	
73233-00042-06	CUTIMED SORBION SANA STERILE 12X12CM WHITE 3 DE (73233-00033-06) SAMPLE NOT FOR SELLING	73233-42
73238-00001-06	CUTIMED SORBION SANA MULTI STAR STERILE D 11CM WHITE 10 EN FR DE NL IT ES PT SV FI NO DA AR	73238-01
73238-00006-06	CUTIMED SORBION SANA MULTI STAR STERILE D 11CM WHITE 3 DE (73238-00001-06) SAMPLE NOT FOR SELLING	73238-06
73238-00009-06	CUTIMED SORBION SANA MULTI STAR STERILE D 17CM 10 DE EN FR ES IT NL PT SV DA NO FI	73238-09
73278-00000-06	CUTIMED SORBION SANA XL STERILE 28X48CM WHITE 5 EN FR DE NL IT ES PT SV FI NO DA AR	73278-00
73278-00001-06	CUTIMED SORBION SANA XL STERILE 28X48CM WHITE 6 DE	73278-01
73278-00002-06	CUTIMED SORBION SANA XL STERILE 28X48CM WHITE 2 DE (73278-00001-06) SAMPLE NOT FOR SELLING	73278-02