

We,

**BSN medical GmbH
Quickbornstr. 24
20253 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:

Cutisoft® Cotton

Basic UDI-DI:

4042809400396069Y

Intended purpose:

Cutisoft® Cotton is intended for skin and wound cleansing, absorption of secretion/exudates and is suitable as a primary or secondary dressing. The device is for short-term use. The use of device is not restricted to a specific patient population.

Conformity assessment route: **Annex II+III**

Classification rule:

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Classification:

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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.

Date of Issue: 07.08.2020

Compiled and released:

Hamburg, 07.08.2020
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
71738-00017-03	CUTISOFT COTTON GAUZE SWAB NON STERILE 10X20CM 50 DA EN FI DE NO SV T17 24PLY	71738-17
72223-00000-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 5X5CM 100 DE EN FR IT NL T17 8PLY	72223-00
72223-00001-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 7.5X7.5CM 100 DE EN FR IT NL T17 8PLY	72223-01
72223-00002-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 10X10CM 100 DE EN FR IT NL T17 8PLY	72223-02
72223-00003-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 10X20CM 100 DE EN FR IT NL T17 8PLY	72223-03
72223-00004-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 20X20CM 100 DE EN FR IT NL T17 8PLY	72223-04
72223-00005-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 5X5CM 100 DE EN FR IT NL T17 12PLY	72223-05
72223-00006-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 7.5X7.5CM 100 DE EN FR IT NL T17 12PLY	72223-06
72223-00007-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 10X10CM 100 DE EN FR IT NL T17 12PLY	72223-07
72223-00008-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 10X12.5CM 100 DE EN FR IT NL T17 12PLY	72223-08
72223-00009-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 10X20CM 100 DE EN FR IT NL T17 12PLY	72223-09
72223-00010-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 5X5CM 100 DE EN FR IT NL T17 16PLY	72223-10
72223-00011-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 7.5X7.5CM 100 DE EN FR IT NL T17 16PLY	72223-11
72223-00012-01	CUTISOFT COTTON GAUZE SWAB NON	72223-12

Article	Description	REF
	STERILE 10X10CM 100 DE EN FR IT NL T17 16PLY	
72223-00013-01	CUTISOFT COTTON GAUZE SWAB NON STERILE 10X20CM 100 DE EN FR IT NL T17 16PLY	72223-13