

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:

Leukoplast® swab ball gauze

Basic UDI-DI:

404280940048588AT

Intended purpose:

**Leukoplast® swab ball gauze is intended for skin and wound cleansing, absorption of secretion/exudates. As mechanical barrier it is suitable as a primary or secondary dressing in order to cover a wound and to provide cushioning.
The device is for short-term use.**

Conformity assessment route: **Annex IX, Chapter I**
Classification rule: **4**
Classification: **Is**

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.

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Compiled and released:

Hamburg, 12.05.2023
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH





Declaration of Conformity
Leukoplast® swab ball
gauze

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Article	Description	REF
71228-00000-00	LEUKOPLAST GAUZE SWAB BALL STERILE WALNUT WHITE 42X2+3 T20	71228-00
71228-00001-00	LEUKOPLAST GAUZE SWAB BALL STERILE PLUM WHITE 42X2+2 T20	71228-01
71228-00002-00	LEUKOPLAST GAUZE SWAB BALL STERILE PLUM WHITE 42X2+3 T20	71228-02
71228-00003-00	LEUKOPLAST GAUZE SWAB BALL STERILE EGG WHITE 16X10 T20	71228-03
71228-00004-00	LEUKOPLAST GAUZE SWAB BALL STERILE EXTRA WHITE 16X10 T20	71228-04
71228-00005-00	LEUKOPLAST GAUZE SWAB BALL STERILE EXTRA WHITE 16X5 T20	71228-05