

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:

404280940048592AJ

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 II+III**
Classification rule: **4**
Classification: **I**

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.

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Compiled and released:

Hamburg, 09.03.2023
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH





Declaration of Conformity
Leukoplast® swab ball
gauze

JBX.40048592.01
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Article	Description	REF
71230-00000-00	LEUKOPLAST GAUZE SWAB BALL NON STERILE WALNUT WHITE 1000X1 DA NL EN FI FR DE HI ID IT NO PT ES SV T20	71230-00
71230-00001-00	LEUKOPLAST GAUZE SWAB BALL NON STERILE PLUM WHITE 1000X1 DA NL EN FI FR DE HI ID IT NO PT ES SV T20	71230-01
71230-00002-00	LEUKOPLAST GAUZE SWAB BALL NON STERILE EGG WHITE 500X1 DA NL EN FI FR DE HI ID IT NO PT ES SV T20	71230-02
71230-00003-00	LEUKOPLAST GAUZE SWAB BALL NON STERILE EXTRA WHITE 500X1 DA NL EN FI FR DE HI ID IT NO PT ES SV T20	71230-03
71230-00004-00	LEUKOPLAST GAUZE SWAB BALL NON STERILE FIST WHITE 250X1 DA NL EN FI FR DE HI ID IT NO PT ES SV T20	71230-04