

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 preparation

Basic UDI-DI:

404280940049859BA

Intended purpose:

Leukoplast® swab preparation is intended for skin and wound cleansing, and absorption of secretion/exudates. It is used for dissection of tissue and anatomical structures during surgery and used inside the body for a surgical incision. The device is for short-term use.

Conformity assessment route: **Annex IX, Chapter I**

Classification rule:

7

Classification:

Ila

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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Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
71290-00000-00	LEUKOPLAST PREPARATION SWAB GAUZE STERILE SMALL WHITE 100X10 DA NL EN FI FR DE HI ID IT NO PT ES SV XR T24	71290-00
71290-00001-00	LEUKOPLAST PREPARATION SWAB GAUZE STERILE MEDIUM WHITE 90X10 DA NL EN FI FR DE HI ID IT NO PT ES SV XR T24	71290-01
71290-00002-00	LEUKOPLAST PREPARATION SWAB GAUZE STERILE LARGE 70X10 DA NL EN FI FR DE HI ID IT NO PT ES SV XR T24	71290-02