

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 abdominal

Basic UDI-DI:

404280940048586AP

Intended purpose:

Leukoplast® swab abdominal is intended for skin and wound cleansing, and absorption of secretion/exudates. It is used for gripping and retaining organs and tissue during surgery, 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
71231-00000-00	LEUKOPLAST ABDOMINAL SWAB X-RAY DETECTABLE STERILE 8X90CM GREEN 24X2 DA NL EN FI FR DE HI ID IT NO PT ES SV T20 4PLY	71231-00
71231-00001-00	LEUKOPLAST ABDOMINAL SWAB X-RAY DETECTABLE STERILE 20X30CM GREEN 14X5 DA NL EN FI FR DE HI ID IT NO PT ES SV T204PLY	71231-01
71231-00002-00	LEUKOPLAST ABDOMINAL SWAB X-RAY DETECTABLE STERILE 45X45CM GREEN 14X2 DA NL EN FI FR DE HI ID IT NO PT ES SV T204PLY	71231-02
71231-00003-00	LEUKOPLAST ABDOMINAL SWAB X-RAY DETECTABLE STERILE 45X45CM GREEN 6X5 DA NL EN FI FR DE HI ID IT NO PT ES SV T204PLY	71231-03
71231-00004-00	LEUKOPLAST ABDOMINAL SWAB X-RAY DETECTABLE STERILE 45X45CM GREEN 12X2 DA NL EN FI FR DE HI ID IT NO PT ES SV T206PLY	71231-04
71231-00005-00	LEUKOPLAST ABDOMINAL SWAB X-RAY DETECTABLE STERILE 45X45CM GREEN 6X5 DA NL EN FI FR DE HI ID IT NO PT ES SV T206PLY	71231-05
71231-00006-00	LEUKOPLAST ABDOMINAL SWAB X-RAY DETECTABLE STERILE 50X60CM GREEN 6X2 DA NL EN FI FR DE HI ID IT NO PT ES SV T206PLY	71231-06
71231-00007-00	LEUKOPLAST ABDOMINAL SWAB X-RAY DETECTABLE STERILE 50X60CM GREEN 8X2 DA NL EN FI FR DE HI ID IT NO PT ES SV T204PLY	71231-07
71231-00008-00	LEUKOPLAST ABDOMINAL SWAB X-RAY DETECTABLE STERILE 8X90CM GREEN 24X2 DA NL EN FI FR DE HI ID IT NO PT ES SV T20 6PLY	71231-08
71231-00009-00	LEUKOPLAST ABDOMINAL SWAB X-RAY DETECTABLE STERILE 20X30CM GREEN 14X5 DA NL EN FI FR DE HI ID IT NO PT ES SV T206PLY	71231-09