

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® Leukosan® Strip

Basic UDI-DI:

404280940049536AF

Intended purpose:

Leukoplast® Leukosan® Strip are sterile, single use wound closure strips intended for closing of topical lacerations and incisions.

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.

Date of Issue: 27.10.2022

Compiled and released:

Hamburg, 27.10.2022
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
71212-00000-01	LEUKOPLAST LEUKOSAN STRIP STERILE 6X38MM WHITE 12 IT PT ES PHARM	71212-00
71212-00001-01	LEUKOPLAST LEUKOSAN STRIP STERILE 6X75MM WHITE 6 IT PT ES PHARM	71212-01
71212-00002-01	LEUKOPLAST LEUKOSAN STRIP STERILE 3X75MM WHITE 10 IT PT ES PHARM	71212-02
79951-00001-03	LEUKOPLAST LEUKOSAN STRIP STERILE 1 POUCH 6 6MMX38MM;1 POUCH 3 6MMX75MM NATURAL 1 NL FR DE IT KIT AT CH FR NL	79951-01
79951-00002-02	LEUKOPLAST LEUKOSAN STRIP STERILE 1 POUCH 6 6MMX38MM;1 POUCH 3 6MMX75MM NATURAL 1 IT PT ES KIT	79951-02
79951-00003-02	LEUKOPLAST LEUKOSAN STRIP STERILE 1 POUCH 6 6MMX38MM;1 POUCH 3 6MMX75MM NATURAL 1 DA EN FI NO SV KIT NORDIC	79951-03