

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).

Prduct Name:

Leukoplast® Soft

Basic UDI-DI: 40428094003553494

Intended purpose:

Leukoplast® soft dressing length is intended for minor wounds like cuts, lacerations, abrasions or as cover of puncture sites after blood withdrawal or vaccination.

Gallin Buila

Conformity assessment route: Annex II+III

Classification rule: Classification:

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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Martin Spengler Director Regulatory Affairs Hamburg BSN medical GmbH



Declaration of Conformity Leukoplast® Soft

Article	Description	REF
79297-00000-01	LEUKOPLAST SOFT 4CMX5M TAN 1 NL EN FI FR DE IT PT ES SV	79297-00
79297-00001-01	LEUKOPLAST SOFT 6CMX5M TAN 1 NL EN FI FR DE IT PT ES SV	79297-01
79297-00002-01	LEUKOPLAST SOFT 8CMX5M TAN 1 NL EN FI FR DE IT PT ES SV	79297-02