

We,

BSN medical GmbH Quickbornstr. 24 20253 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:

4042809400355318W

Intended purpose:

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

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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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Hamburg, 26.03.2021

Martin Spengler Director Regulatory Affairs Hamburg BSN medical GmbH



Declaration of Conformity Leukoplast® soft

JBX.40035531.02 Page 2 of 2

Article	Description	REF
79297-00003-01	LEUKOPLAST SOFT 19X72MM TAN 100 NL EN FI FR DE IT PT ES SV	79297-03
79297-00004-01	LEUKOPLAST SOFT 28X72MM TAN 100 NL EN FI FR DE IT PT ES SV	79297-04