

We,

BSN medical GmbH
Quickbornstrasse 24
20253 Hamburg
Germany
(SRN: not issued yet)

hereby declare under our own responsibility, that this product family complies with the applicable regulations of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product name: **Leukoplast® soft white**
Basic UDI-DI: **(not defined yet)**
Intended purpose: **Refer to clinical evaluation**
Conformity assessment route: **Annex II+III**
Classification rule: **4**
Classification: **I**

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.

Certificate No 50708-14-00 (EN ISO 13485)

Date of Issue: 16.01.2020

Compiled and released:

Hamburg, 16.01.2020
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
76450-00003-00	LEUKOPLAST SOFT WHITE 19X72MM 100 DE DA EN FI FR IT NL NO PT SV ES	76450-03
76450-00004-00	LEUKOPLAST SOFT WHITE 38X72MM 100 DE DA EN FI FR IT NL NO PT SV ES	76450-04
76450-00012-00	LEUKOPLAST SOFT WHITE 12 19MX72MM, 8 38X72MM 1 IT PT ES (20DRS 2SIZES)	76450-12
76450-00013-00	LEUKOPLAST SOFT WHITE 12 19MX72MM, 8 38X72MM 1 NL FR DE IT CENTRAL (20DRS 2SIZES)	76450-13
76450-00014-00	LEUKOPLAST SOFT WHITE 12 19MX72MM, 8 38X72MM 1 DA EN FI NO SV NORDIC (20DRS 2SIZES)	76450-14
76450-00015-00	LEUKOPLAST SOFT WHITE 38X72MM 10 IT PT ES	76450-15
76450-00016-00	LEUKOPLAST SOFT WHITE 38X72MM 10 NL FR DE	76450-16
76450-00017-00	LEUKOPLAST SOFT WHITE 38X72MM 10 EN FI SV	76450-17
76450-00018-00	LEUKOPLAST SOFT WHITE 19X72MM 20 IT PT ES	76450-18
76450-00019-00	LEUKOPLAST SOFT WHITE 19X72MM 20 EN FI SV	76450-19
76450-00020-00	LEUKOPLAST SOFT WHITE 16 19MX72MM, 10 D22MM, 6 38X38MM, 8 38X72MM 1 IT PT ES (40DRS 4SIZES)	76450-20
76450-00021-00	LEUKOPLAST SOFT WHITE 12 19X72MM, 6 D22MM, 8 38X72MM, 4 38X38MM 1 NL FR DE IT CENTRAL (30DRS 4SIZES)	76450-21
76450-00022-00	LEUKOPLAST SOFT WHITE 12 19X72MM, 6 D22MM, 8 38X72MM, 4 38X38MM 1 DA EN FI NO SV NORDIC (30DRS 4SIZES)	76450-22
76450-00023-00	LEUKOPLAST SOFT WHITE 38X38MM 1000 DE DA EN FI FR IT NL NO PT SV ES	76450-23
76450-00024-00	LEUKOPLAST SOFT WHITE 19X72MM 1000 DE DA EN FI FR IT NL NO PT SV ES	76450-24
76450-00025-00	LEUKOPLAST SOFT WHITE 38X72MM 1000 DE DA EN FI FR IT NL NO PT SV ES	76450-25

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Product name: **Leukoplast® soft white**
Basic UDI-DI: **4042809400332127V**

Intended purpose: **Leukoplast® soft white products are intended for short time use as cover for minor wounds like cuts, lacerations, abrasions or as cover of puncture sites after blood withdrawal or vaccination.**

Conformity assessment route: **Annex II+III**
Classification rule: **4**
Classification: **I**

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Date of Issue: 27.04.2020

Compiled and released:

Hamburg, 27.04.2020
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
76450-00005-00	LEUKOPLAST SOFT WHITE 4X10CM 5 DE NL FR	76450-05
76450-00006-00	LEUKOPLAST SOFT WHITE 6X10CM 5 DE NL FR	76450-06
76450-00007-00	LEUKOPLAST SOFT WHITE 6X10CM 10 IT PT ES	76450-07
76450-00008-00	LEUKOPLAST SOFT WHITE 6X10CM 10 DE NL FR	76450-08
76450-00009-00	LEUKOPLAST SOFT WHITE 8X10CM 5 DE NL FR	76450-09
76450-00010-00	LEUKOPLAST SOFT WHITE 8X10CM 10 IT PT ES	76450-10
76450-00011-00	LEUKOPLAST SOFT WHITE 8X10CM 10 NL FR DE	76450-11
76450-00027-00	LEUKOPLAST SOFT WHITE 6X10CM 10 EN FI SV	76450-27

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Product name: **Leukoplast® soft white**
Basic UDI-DI: **(not defined yet)**
Intended purpose: **Refer to clinical evaluation**
Conformity assessment route: **Annex II+III**
Classification rule: **4**
Classification: **I**

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Hamburg, 16.01.2020
Martin Spengler
Director Regulatory Affairs Hamburg
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Article	Description	REF
76450-00026-00	LEUKOPLAST SOFT WHITE 19X40MM 500 DE DA EN FI FR IT NL NO PT SV ES INJECTION DRESSING	76450-26

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Product name: **Leukoplast® soft white**
Basic UDI-DI: **4042809400355379A**

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

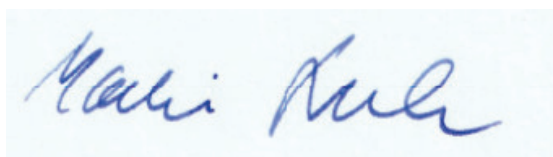
Conformity assessment route: **Annex II+III**
Classification rule: **4**
Classification: **I**

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Compiled and released:

Hamburg, 07.04.2020
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
76450-00000-00	LEUKOPLAST SOFT WHITE 4CMX5M 1 DA NL EN FI FR DE IT NO PT ES SV	76450-00
76450-00001-00	LEUKOPLAST SOFT WHITE 6CMX5M 1 DA NL EN FI FR DE IT NO PT ES SV	76450-01
76450-00002-00	LEUKOPLAST SOFT WHITE 8CMX5M 1 DA NL EN FI FR DE IT NO PT ES SV	76450-02