

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: **Leukosilk®**
Basic UDI-DI: **40428094003457295**

Intended purpose: **Leukosilk® is intended for short time use on intact skin for fixation of dressings of all types and sizes and for fixation and securing of tubes, catheters, probes and cannulae.**

Conformity assessment route: **Annex II+III**
Classification rule: **1**
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.

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Compiled and released:

Hamburg, 17.08.2020
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
01021-00000-12	LEUKOSILK PLASTIC SNAP RING 1.25CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO ES SV 24/BOX	01021-00
01021-00002-03	LEUKOSILK PLASTIC SNAP RING BLISTERCARD 1.25CMX5M WHITE 1 NL FR DE	01021-02
01021-00004-12	LEUKOSILK PLASTIC SNAP RING 1.25CMX5M WHITE 1 IT LABEL 01021-00	01021-04
01022-00000-12	LEUKOSILK PLASTIC SNAP RING 2.5CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO ES SV 12/BOX	01022-00
01022-00002-12	LEUKOSILK PLASTIC SNAP RING 2.5CMX5M WHITE 1 IT LABELED 01022-00	01022-02
01022-00003-03	LEUKOSILK PLASTIC SNAP RING BLISTERCARD 2.5CMX5M WHITE 1 NL FR DE	01022-03
01024-00000-12	LEUKOSILK PLASTIC SNAP RING 5CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO ES SV 6/BOX	01024-00
01024-00001-12	LEUKOSILK PLASTIC SNAP RING 5CMX5M WHITE 1 IT LABELED 01024-00	01024-01
01031-00000-12	LEUKOSILK PLASTIC SPOOL 1.25CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO ES SV 24/BOX	01031-00
01032-00000-12	LEUKOSILK PLASTIC SPOOL 2.5CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO ES SV 12/BOX	01032-00
01034-00000-12	LEUKOSILK PLASTIC SPOOL 5CMX5M WHITE 1 DA NL EN FI FR DE EL IT NO ES SV 6/BOX	01034-00
09566-00000-03	LEUKOSILK PLASTIC SPOOL 1.25CMX9.2M WHITE 1 DA NL EN FI FR DE EL IT NO ES SV 24/BOX	09566-00
09567-00000-03	LEUKOSILK PLASTIC SPOOL 2.5CMX9.2M WHITE 1 DA NL EN FI FR DE EL IT NO ES SV 12/BOX	09567-00
09569-00000-03	LEUKOSILK PLASTIC SPOOL 5CMX9.2M WHITE 1 DA NL EN FI FR DE EL IT NO ES SV 6/BOX	09569-00
72669-00000-02	LEUKOSILK PLASTIC SNAP RING 1.25CMX4.6M WHITE 1 EN FR EL ES 24/BOX	72669-00

Article	Description	REF
72669-00001-02	LEUKOSILK PLASTIC SNAP RING 2.5CMX4.6M WHITE 1 EN FR EL ES 12/BOX	72669-01
72669-00002-02	LEUKOSILK PLASTIC SNAP RING 5CMX4.6M WHITE 1 EN FR EL ES 6/BOX	72669-02