

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:

Leukoflex®

Basic UDI-DI:

4042809400345759B

Intended purpose:

Leukoflex® is intended for short time use on intact skin for fixation of dressings of all types and sizes, fixation of occlusive dressings and for fixation and securing of catheters, probes and cannulae.

Conformity assessment route: **Annex II+III**

Classification rule:

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Classification:

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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, 10.08.2023
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
01121-00000-12	LEUKOFLEX PLASTIC SNAP RING 1.25CMX5M TRANSPARENT 1 DA NL EN FI FR DE EL IT NO ES SV 24/BOX	01121-00
01122-00000-12	LEUKOFLEX PLASTIC SNAP RING 2.5CMX5M TRANSPARENT 1 DA NL EN FI FR DE EL IT NO ES SV 12/BOX	01122-00
01124-00000-12	LEUKOFLEX PLASTIC SNAP RING 5CMX5M TRANSPARENT 1 DA NL EN FI FR DE EL IT NO ES SV 6/BOX	01124-00
01131-00000-12	LEUKOFLEX PLASTIC SPOOL 1.25CMX5M TRANSPARENT 1 DA NL EN FI FR DE EL IT NO ES SV 24/BOX	01131-00
01132-00000-12	LEUKOFLEX PLASTIC SPOOL 2.5CMX5M TRANSPARENT 1 DA NL EN FI FR DE EL IT NO ES SV 12/BOX	01132-00
01134-00000-12	LEUKOFLEX PLASTIC SPOOL 5CMX5M TRANSPARENT 1 DA NL EN FI FR DE EL IT NO ES SV 6/BOX	01134-00