

We,

**BSN medical GmbH
Quickbornstr. 24
20253 Hamburg
Germany
(SRN: DE-MF-000005787)**

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: **Leukofix®**
Basic UDI-DI: **4042809400328168U**

Intended purpose: **Leukofix® 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: **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.

Date of Issue: 17.06.2021

Compiled and released:

Hamburg, 17.06.2021
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
02121-00000-12	LEUKOFIX PLASTIC SNAP RING 1.25CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 24/BOX	02121-00
02122-00000-12	LEUKOFIX PLASTIC SNAP RING 2.5CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 12/BOX	02122-00
02124-00000-12	LEUKOFIX PLASTIC SNAP RING 5CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 6/BOX	02124-00
02131-00000-12	LEUKOFIX PLASTIC SPOOL 1.25CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 24/BOX	02131-00
02132-00000-12	LEUKOFIX PLASTIC SPOOL 2.5CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 12/BOX	02132-00
02134-00000-12	LEUKOFIX PLASTIC SPOOL 5CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 6/BOX	02134-00
02136-00000-10	LEUKOFIX PLASTIC CORE 1.25CMX9.2M 1 DA NL EN FI FR DE EL IT NO PT ES SV 24/BOX	02136-00
02137-00000-10	LEUKOFIX PLASTIC CORE 2.5CMX9.2M 1 DA NL EN FI FR DE EL IT NO PT ES SV 12/BOX	02137-00
02138-00000-10	LEUKOFIX PLASTIC CORE 5.0CMX9.2M 1 DA NL EN FI FR DE EL IT NO PT ES SV 6/BOX	02138-00