

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:

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.

Declaration of conformity issued: 01.07.2024

Compiled and released:

Hamburg, 01.07.2024
Martin Spengler
Director Regulatory Affairs Hamburg
BSN medical GmbH



Article	Description	REF
02121-00000-13	LEUKOFIX PLASTIC SNAP RING 1.25CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 24/BOX	02121-00
02122-00000-13	LEUKOFIX PLASTIC SNAP RING 2.5CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 12/BOX	02122-00
02124-00000-13	LEUKOFIX PLASTIC SNAP RING 5CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 6/BOX	02124-00
02131-00000-13	LEUKOFIX PLASTIC SPOOL 1.25CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 24/BOX	02131-00
02132-00000-13	LEUKOFIX PLASTIC SPOOL 2.5CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 12/BOX	02132-00
02134-00000-13	LEUKOFIX PLASTIC SPOOL 5CMX5M 1 DA NL EN FI FR DE EL IT NO ES SV 6/BOX	02134-00
02136-00000-11	LEUKOFIX PLASTIC CORE 1.25CMX9.2M 1 DA NL EN FI FR DE EL IT NO PT ES SV 24/BOX	02136-00
02137-00000-11	LEUKOFIX PLASTIC CORE 2.5CMX9.2M 1 DA NL EN FI FR DE EL IT NO PT ES SV 12/BOX	02137-00
02138-00000-11	LEUKOFIX PLASTIC CORE 5.0CMX9.2M 1 DA NL EN FI FR DE EL IT NO PT ES SV 6/BOX	02138-00