

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: **Leukofix®**
Basic UDI-DI: **(not defined yet)**
Intended purpose: **Refer to clinical evaluation**
Conformity assessment route: **Annex II+III**
Classification rule: **1**
Classification: **I**

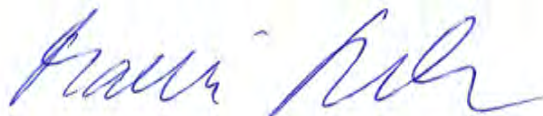
The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

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

Date of Issue: 25.02.2020

Compiled and released:

Hamburg, 25.02.2020
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