

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: **Leukomed® T skin sensitive**

Basic UDI-DI: **404280940046856AF**

Intended purpose: **Leukomed® T skin sensitive is intended for the fixation of wound dressings and additional fixation of devices (catheters, cannulas), and for the coverage of acute wounds, such as closed surgical wounds, cuts and abrasions. It is especially suitable for fragile and sensitive skin.**

Conformity assessment route: **Annex IX, Chapter I+III**
Classification rule: **4**
Classification: **Is**


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.
This declaration is only valid in conjunction with the current E.C. certificates issued by DEKRA Certification GmbH (Id. No. 0124), Handwerkstraße 15, 70565 Stuttgart, Germany.

Number of E.C. certificate: 50708-60-05

Declaration of conformity issued: 20.09.2024

Compiled and released:

Hamburg, 20.09.2024
Dr. Thomas Mehler
Global Quality Director Medical
BSN medical GmbH

 Digitally signed by
Thomas.Mehler
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Date: 2024.09.20
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Article	Description	REF
76464-00000-02	LEUKOMED T SKIN SENSITIVE STERILE 5X7.2CM TRANSPARENT 5 DA NL EN FI FR DE IT JA NO PT ES SV	76464-00
76464-00001-02	LEUKOMED T SKIN SENSITIVE STERILE 8X10CM TRANSPARENT 5 DA NL EN FI FR DE IT JA NO PT ES SV	76464-01
76464-00002-02	LEUKOMED T SKIN SENSITIVE STERILE 8X15CM TRANSPARENT 5 DA NL EN FI FR DE IT JA NO PT ES SV	76464-02