

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® I.V. film

Basic UDI-DI:

4042809400416508N

Intended purpose:

Leukomed® I.V. film is intended for fixation of I.V. catheters and covering and protection of puncture sites.

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
DN: cn=Thomas.Mehler
Date: 2024.09.20
09:48:11 +02'00'

Article	Description	REF
72390-00000-05	LEUKOMED INTRAVENOUS STERILE 6X8CM TRANSPARENT 50 DA NL EN FI FR DE IT NO PT ES SV HOSP.	72390-00
72390-00003-05	LEUKOMED INTRAVENOUS STERILE 8.5X11.5CM TRANSPARENT 50 DA NL EN FI FR DE IT NO PT ES SV HOSP.	72390-03
72390-00004-05	LEUKOMED INTRAVENOUS STERILE 4.5X4.5CM TRANSPARENT 50 DA NL EN FI FR DE IT NO PT ES SV HOSP.	72390-04
72390-00005-05	LEUKOMED INTRAVENOUS STERILE 7X9CM TRANSPARENT 50 DA NL EN FI FR DE IT NO PT ES SV HOSP.	72390-05