Konformitätserklärung
Declaration of Conformity

Wir | We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
DE-MF-000000201

erklären in eigener Verantwortung, dass das/die Produkt/e

hereby declare in our own responsibility that the product/s

Infusomat® Plus Line
Nur für die Regionalanästhesie.
Zur Verwendung mit geeigneten Pumpen oder Schwerkraft.

Infusomat® Plus Line
For Regional Anesthesia only. For application by compatible pumps or gravity.

(Artikelnummern und Basic UDI-DI siehe Anlage I)

(article and Basic UDI-DI numbers see attachment I)

mit den Anforderungen der Medizinprodukte Verordnung (EU) 2017/745 übereinstimmt/übereinstimmen

is/are in conformity with the requirements of the Medical Device Regulation (EU) 2017/745

Konformitätsbewertungsverfahren
nach Anhang IX

Conformity Assessment Procedure
according to annex IX

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse IIa

Classification
according to annex VIII of the Regulation named above
Class IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Gültig bis
gemäß gültigem EU Zertifikat
(Nr. G10 012974 0611)

Valid until
according to our valid EU Certificate
(No. G10 012974 0611)

Effective

Anlage I / Attachment I

Basic UDI-DI: 403923900000008642Z

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8700410	Infusomat® Plus Line	IIa

Effective

Document amendment information

Version	Description of the changes
1.0	Initial Version under MDR.

Effective

Title: Declaration of Conformity - 097-008 - MDR - Infusomat Plus Line Initiator: Daniela ? Schul

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Schul, Daniela (schudnde)
Title: Senior Manager Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 31 January 2024, 15:50 W. Europe Daylight Time
Meaning: Document signed as Author
==========

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 31 January 2024, 17:56 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Thursday, 01 February 2024, 15:12 W. Europe Daylight Time
Meaning: Approve Document
==========

Effective