

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

(Artikelnummern und Basic UDI-DI siehe Anlage I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/übereinstimmen**Konformitätsbewertungsverfahren**
nach Anhang IX**Klassifizierung**gemäß Anhang VIII der oben genannten
Verordnung
Klasse IIa**Benannte Stelle**TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**gemäß gültigem EU Zertifikat
(Nr. G10 012974 0611)hereby declare in our own responsibility
that the product/s**Infusomat® Space Line**For Regional Anesthesia only. For application by
compatible pumps or gravity.

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

is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745**Conformity Assessment Procedure**
according to annex IX**Classification**according to annex VIII of the Regulation named
above
Class IIa**Notified Body**TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**according to our valid EU Certificate
(No. G10 012974 0611)

Anlage I / Attachment I

Basic UDI-DI: 4039239000008693B

Art.-Nr. / Art. No.	Produktname / Product name
8700132SP	Infusomat® Space Line

Klasse / Class
Ila

Document amendment information

Version	Description of the changes
1.0	Initial Version under MDR.

Title: Declaration of Conformity - 097-007 - MDR - Infusomat Space 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, 15:49 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, 17:55 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, 15:06 W. Europe Daylight Time
Meaning: Approve Document
=====