

## Konformitätserklärung Declaration of Conformity

Wir

We

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

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

hereby declare in our own responsibility  
that the product/s

### **Infusomat® Space Line**

Nur für die enterale Ernährung. Für die  
Applikation mittels kompatibler Pumpen oder  
Schwerkraft.

**Infusomat® Space Line**  
For enteral nutrition only. For application by  
compatible pumps or gravity.

(Artikelnummern und Basic UDI-DI siehe Anlage I)

(article numbers and Basic UDI-DI 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  
der oben genannten Verordnung

**Conformity Assessment Procedure**  
according to annex IX  
of the Regulation named above

**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)

### Anlage I / Attachment I

**Basic UDI-DI 403923900000086839**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
----------------------------	-----------------------------------	-----------------------

8250832SP	Infusomat® Space Line	IIa
-----------	-----------------------	-----

8250834SP	Infusomat® Space Line	IIa
-----------	-----------------------	-----

#### Document amendment information

Version	Description of the changes
1.0	Initial version.

Title: Declaration of Conformity - 097-003 - MDR - Infusomat Space Lines (Enteral Safety) 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: Thursday, 07 March 2024, 08:48 W. Europe Daylight Time  
Meaning: Document signed as Author

---

UserName: Seidel, Stefan (seidstde)  
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy  
Date: Thursday, 07 March 2024, 14:08 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, 07 March 2024, 14:14 W. Europe Daylight Time  
Meaning: Approve Document

---