

**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  
Infusomat® Space Line SafeSet**  
Infusionsgerät. Zur Infusion 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  
der oben genannten Verordnung**Klassifizierung**  
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  
Infusomat® Space Line SafeSet**  
I.V. administration set. For infusion by gravity  
and compatible pumps.

(article numbers and Basic UDI-DI 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  
of the Regulation named above**Classification**  
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: 40392390000086737**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8700036SP	Infusomat® Space Line	Ila
8700435SP	Infusomat® Space Line	Ila
8270350SP-01	Infusomat® Space Line	Ila
8270350SP-26	Infusomat® Space Line	Ila
8701148SP	Infusomat® Space Line SafeSet	Ila
8270358SP-01	Infusomat® Space Line SafeSet	Ila
8270358SP-26	Infusomat® Space Line SafeSet	Ila
8270350SP	Infusomat® Space Line	Ila
8270358SP	Infusomat® Space Line SafeSet	Ila
8250720SP	Infusomat® Space Line SafeSet	Ila
8700087SP-01	Infusomat® Space Line	Ila
8700087SP-26	Infusomat® Space Line	Ila
8700130SP	Infusomat® Space Line SafeSet	Ila
8700131SP	Infusomat® Space Line	Ila
8250710SP	Infusomat® Space Line	Ila
8250718SP	Infusomat® Space Line SafeSet	Ila
8250719SP	Infusomat® Space Line SafeSet	Ila
8250731SP	Infusomat® Space Line	Ila
8700095SP	Infusomat® Space Line	Ila
8700098SP	Infusomat® Space Line SafeSet	Ila
8700110SP	Infusomat® Space Line	Ila
8700118SP	Infusomat® Space Line SafeSet	Ila
8701149SP	Infusomat® Space Line SafeSet	Ila

**Basic UDI-DI: 40392390000014792Z**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8250437SP	Infusomat® Space Line	Ila
8250438SP	Infusomat® Space Line SafeSet	Ila
8700127SP	Infusomat® Space Line	Ila
8700128SP	Infusomat® Space Line SafeSet	Ila

### Document amendment information

Version	Description of the changes
1.0	Initial version.
2.0	Addition of art. no. 8270350SP, 8270358SP, 8250720SP, 8700087SP-01, 8700087SP-26, 8700130SP, 8700131SP, 8250710SP, 8250718SP, 8250719SP, 8250731SP, 8700095SP, 8700098SP, 8700110SP, 8700118SP, 8701149SP Addition of art. no. 8250437SP, 8250438SP, 8700127SP, 8700128SP

Title: Declaration of Conformity - 097-001 - MDR - Infusomat Space Lines Initiator: Daniela ? Schul

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

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