

## 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

**Infusomat® Plus Line,**  
**Infusomat® Plus Line SafeSet**  
Infusionsgerät. Für die Verwendung für  
Schwerkraftinfusionen und mit geeigneten  
Infusionspumpen.

(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® Plus Line,**  
**Infusomat® Plus 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 4039239000008622V**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8700200	Infusomat® Plus Line SafeSet	IIa
8700200-20	Infusomat® Plus Line SafeSet	IIa
8700210	Infusomat® Plus Line SafeSet	IIa
8700310	Infusomat® Plus Line	IIa
8700310-20	Infusomat® Plus Line	IIa
8700310CN	Infusomat® Plus Line	IIa
8700240-20	Infusomat® Plus Line SafeSet	IIa
8700240	Infusomat® Plus Line SafeSet	IIa
8700330CN	Infusomat® Plus Line	IIa
8700340CN	Infusomat® Plus Line	IIa
8700330	Infusomat® Plus Line	IIa
8700340	Infusomat® Plus Line	IIa
8700220	Infusomat® Plus Line SafeSet	IIa
8700250	Infusomat® Plus Line SafeSet	IIa
8700280	Infusomat® Plus Line SafeSet	IIa
8700300	Infusomat® Plus Line SafeSet	IIa
8700320	Infusomat® Plus Line	IIa

**Basic UDI-DI 4039239000008622V**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8700260	Infusomat® Plus Line SafeSet	IIa
8700270	Infusomat® Plus Line SafeSet	IIa
8700260-20	Infusomat® Plus Line SafeSet	IIa

### Document amendment information

Version	Description of the changes
1.0	Initial version.
2.0	Addition of art. no. 8700240-20, 8700240, 8700330CN, 8700340CN, 8700330, 8700340 8700220, 8700250, 8700280, 8700300, 8700320 Addition of Basic UDI-DI 40392390000020742A with article numbers 8700260, 8700270 8700260-20

Title: Declaration of Conformity - 097-005 - MDR - Infusomat Plus 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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