

**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 40392390000008622V**

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

Basic UDI-DI 403923900000020742A

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8700260	Infusomat® Plus Line SafeSet	Ila
8700270	Infusomat® Plus Line SafeSet	Ila
8700260-20	Infusomat® Plus Line SafeSet	Ila

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
3.0	Correction of Basic UDI-DI of article numbers 8700260, 8700270 and 8700260-20 from 40392390000008622V to 40392390000020742A.

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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