

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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