Konformitätserklärung
Declaration of Conformity

Wir | We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

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

hereby declare in our own responsibility that the product/s

Infusomat® Plus Line

Infusomat® Plus Line

Set zur Verabreichung von enteraler Ernährung

Administration set for enteral nutrition

(Artikelnummern siehe Anlage I)

(article numbers see attachment I)

mit den Anforderungen der folgenden Richtlinie übereinstimmt/übereinstimmen

is/are in compliance with the following directive

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4)

Conformity Assessment Procedure
according to annex II (excluding section 4)

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa

Classification
according to annex IX of the
Council Directive named above
Class IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123

Notified Body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Datum der ersten CE-Kennzeichnung
2017-08

Date of first CE-marking
2017-08

Gültig bis
2024-05-26

Valid until
2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8700370	Infusomat® Plus Line	IIa
8700370CN	Infusomat® Plus Line	IIa
8700380	Infusomat® Plus Line	IIa
8700400	Infusomat® Plus Line	IIa

Effective

Amendment Information

Version	Description of the changes
01	Add art. no. 8700370, 8700380, 8700400
02	Add art. no. 8700370CN

Effective

Title: Declaration of Conformity - 097-006 - Infusomat Plus Lines (Enteral Safety) Initiator: Caroline ? Herbst

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

UserName: Herbst, Caroline (fuehcade)
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Meaning: Document signed as Author
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UserName: Brand, Thomas (brantode)
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