

**Konformitätserklärung
Declaration of Conformity**

Wir

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

We

erklären in eigener Verantwortung,
dass das/die Produkt/e**Infusomat® Space Line,
Infusomat® Space Line SafeSet,
Infusomat® Plus Line,
Infusomat® Plus Line SafeSet,
Original Infusomat® Line,
Original Infusomat®-Leitung,
Original-Infusomat®-Leitung,
Original Infusomat®-Leitung TK 2000,
Infusomat® Set with Safflow**

Infusionspumpenbestecke

Sangofix®

Transfusionsgeräte mit und ohne Belüftung

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni
1993über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIahereby declare in our own responsibility
that the product/s**Infusomat® Space Line,
Infusomat® Space Line SafeSet,
Infusomat® Plus Line,
Infusomat® Plus Line SafeSet,
Original Infusomat® Line,
Original Infusomat®-Leitung,
Original-Infusomat®-Leitung,
Original Infusomat®-Leitung TK 2000,
Infusomat® Set with Safflow**

Infusion Pump Administration Sets

Sangofix®Blood administration sets vented and non-
vented

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June
1993concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according to annex II (excluding section 4)
of the Council Directive named above**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

Datum der ersten CE-Kennzeichnung

Original-Infusomat®-Leitungen	1994-12
Infusomat® Space Lines	2004-07
Sangofix®	1994-12
Infusomat® Plus Line	2017-08

Gültig bis

2024-05-26

Notified Body

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

Date of first CE-marking

Original-Infusomat®-Tubings	1994-12
Infusomat® Space Lines	2004-07
Sangofix®	1994-12
Infusomat® Plus Line	2017-08

Valid until

2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4062866	Sangofix®	Ila
8250245SP	Infusomat® Space Line	Ila
8250294SP	Infusomat® Space Line	Ila
8250437SP	Infusomat® Space Line	Ila
8250438SP	Infusomat® Space Line SafeSet	Ila
8250710SP	Infusomat® Space Line	Ila
8250715	Original-Infusomat®-Leitung	Ila
8250715SP	Infusomat® Space Line	Ila
8250718SP	Infusomat® Space Line SafeSet	Ila
8250719SP	Infusomat® Space Line SafeSet	Ila
8250720SP	Infusomat® Space Line SafeSet	Ila
8250731SP	Infusomat® Space Line	Ila
8250731T	Original Infusomat® Line	Ila
8270066SP-26	Infusomat® Space Line	Ila
8270066SP-01	Infusomat® Space Line	Ila
8270066SP	Infusomat® Space Line	Ila
8270066T	Original Infusomat® Line	Ila
8270067SP	Infusomat® Space Line	Ila
8270074SP	Infusomat® Space Line	Ila
8270350SP	Infusomat® Space Line	Ila
8270358SP	Infusomat® Space Line SafeSet	Ila
8700036	Original-Infusomat®-Leitung	Ila
8700036SP	Infusomat® Space Line	Ila
8700036T	Original Infusomat® Line	Ila
8700037SP	Infusomat® Space Line	Ila
8700087SP-26	Infusomat® Space Line	Ila
8700087SP-01	Infusomat® Space Line	Ila
8700087SP	Infusomat® Space Line	Ila
8700087T	Original Infusomat®-Leitung TK 2000	Ila
8700095NT	Original Infusomat® Line	Ila
8700095SP	Infusomat® Space Line	Ila
8700098SP	Infusomat® Space Line SafeSet	Ila
8700110SP	Infusomat® Space Line	Ila
8700118SP	Infusomat® Space Line SafeSet	Ila
8700125SP	Infusomat® Space Line	Ila
8700127SP	Infusomat® Space Line	Ila
8700128SP	Infusomat® Space Line SafeSet	Ila
8700130SP	Infusomat® Space Line SafeSet	Ila
8700131SP	Infusomat® Space Line	Ila
8700132SP	Infusomat® Space Line	Ila
8700140SP	Infusomat® Space Line SafeSet	Ila
8700141SP	Infusomat® Space Line SafeSet	Ila
8700142SP	Infusomat® Space Line SafeSet	Ila
8700200-20	Infusomat® Plus Line SafeSet	Ila
8700200	Infusomat® Plus Line SafeSet	Ila
8700210	Infusomat® Plus Line SafeSet	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8700220	Infusomat® Plus Line SafeSet	Ila
8700240-20	Infusomat® Plus Line SafeSet	Ila
8700240	Infusomat® Plus Line SafeSet	Ila
8700260-20	Infusomat® Plus Line SafeSet	Ila
8700250	Infusomat® Plus Line SafeSet	Ila
8700260	Infusomat® Plus Line SafeSet	Ila
8700270	Infusomat® Plus Line SafeSet	Ila
8700280	Infusomat® Plus Line SafeSet	Ila
8700310-20	Infusomat® Plus Line	Ila
8700300	Infusomat® Plus Line SafeSet	Ila
8700310	Infusomat® Plus Line	Ila
8700310CN	Infusomat® Plus Line	Ila
8700320	Infusomat® Plus Line	Ila
8700350-26	Infusomat® Plus Line	Ila
8700330	Infusomat® Plus Line	Ila
8700330CN	Infusomat® Plus Line	Ila
8700350-20	Infusomat® Plus Line	Ila
8700340	Infusomat® Plus Line	Ila
8700340CN	Infusomat® Plus Line	Ila
8700350-01	Infusomat® Plus Line	Ila
8700350	Infusomat® Plus Line	Ila
8700350CN	Infusomat® Plus Line	Ila
8700360	Infusomat® Plus Line	Ila
8700390	Infusomat®plus Line SafeSet	Ila
8700391	Infusomat®plus Line SafeSet	Ila
8700392	Infusomat®plus Line SafeSet	Ila
8700410	Infusomat® Plus Line	Ila
8700435SP	Infusomat® Space Line	Ila
8701148SP	Infusomat® Space Line SafeSet	Ila
8701149SP	Infusomat® Space Line SafeSet	Ila
8751668	Original Infusomat®-Leitung	Ila
8751668SP	Infusomat® Space Line	Ila
8751669SP	Infusomat® Space Line	Ila

Amendment Information

Version	Description of changes
37.0	Add art. no. 8700140SP
38.0	Add art. no. 8700141SP
39.0	Add art. no. 8700390, 8700391
40.0	Delete out of market art. no. 8250898SP
41.0	Add art. no. 8700142SP, 87000392
42.0	Change art. no. from "87000392" to "8700392"

Title: Declaration of Conformity - 39.05.018 - Infusomat Lines 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)
Title: Administrator Regulatory Affairs
Date: Monday, 12 April 2021, 13:07 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Monday, 12 April 2021, 16:31 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Jedelhauser, Ulrich (jedeulde)
Title: Senior Manager Regulatory Affairs CoE IV-Systems / CoE IV Access
Date: Monday, 12 April 2021, 17:32 W. Europe Daylight Time
Meaning: Approve Document
=====