

**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**Infusomat® Space Line**

Set zur Verabreichung von enteraler Ernährung

(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)**Klassifizierung**  
gemäß Anhang IX der  
oben genannten Richtlinie  
Klasse IIa**Benannte Stelle**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Deutschland  
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**  
2013-07**Gültig bis**  
2024-05-26hereby declare in our own responsibility  
that the product/s**Infusomat® Space Line**

Administration set for enteral nutrition

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14<sup>th</sup> June  
1993concerning Medical Devices  
amended by Directive 2007/47/EC**Conformity Assessment Procedure**  
according to annex II (excluding section 4)**Classification**  
according to annex IX of the  
Council Directive named above  
Class IIa**Notified Body**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Germany  
Identification number 0123**Date of first CE-marking**  
2013-07**Valid until**  
2024-05-26

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8250830SP	Infusomat® Space Line	Ila
8250831SP	Infusomat® Space Line	Ila
8250832SP	Infusomat® Space Line	Ila
8250833SP	Infusomat® Space Line	Ila
8250834SP	Infusomat® Space Line	Ila
8250835SP	Infusomat® Space Line	Ila
8250836SP	Infusomat® Space Line	Ila
8250856SP	Infusomat® Space Line	Ila
8250858SP	Infusomat® Space Line	Ila
8250859SP	Infusomat® Space Line	Ila

**Amendment Information**

Version	Description of the changes
06	Add art. no. 8250830SP, 8250832SP, 8250834SP, 8250831SP, 8250833SP, 8250835SP
07	Update validity

Title: Declaration of Conformity - 097-003 - Infusomat Space 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:

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