

**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**Infusionsleitung PE,**  
**Infusions-Leitung PE,**  
**Original Perfusor<sup>®</sup> Leitung,**  
**Original Perfusor<sup>®</sup>-Leitung,**  
**Original-Perfusor<sup>®</sup> Leitung PCA,**  
**Original Perfusor<sup>®</sup>-Leitung Typ: MR,**  
**Original Perfusor<sup>®</sup>-Leitung Typ: MK,**  
**Original Perfusor<sup>®</sup> Line,**  
**Original Perfusor<sup>®</sup> Tubing PE,**  
**Sistema para perfusão/Système de perfusion**Verlängerungsleitungen  
(Artikelnummern siehe Anlage I)mit den Anforderungen der folgenden Richtlinie  
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni 1993  
über 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 IIa**Benannte Stelle**  
TÜV SÜD Product Service GmbH  
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**  
1994-12**Gültig bis**  
2020-09-03hereby declare in our own responsibility  
that the product/s**Infusionsleitung PE,**  
**Infusions-Leitung PE,**  
**Original Perfusor<sup>®</sup> Leitung,**  
**Original Perfusor<sup>®</sup>-Leitung,**  
**Original-Perfusor<sup>®</sup> Leitung PCA,**  
**Original Perfusor<sup>®</sup>-Leitung Typ: MR,**  
**Original Perfusor<sup>®</sup>-Leitung Typ: MK,**  
**Original Perfusor<sup>®</sup> Line,**  
**Original Perfusor<sup>®</sup> Tubing PE,**  
**Sistema para perfusão/Système de perfusion**Extension Fluid Lines  
(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14<sup>th</sup> June 1993  
concerning 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**Notified Body**  
TÜV SÜD Product Service GmbH  
Identification number 0123**Date of first CE-marking**  
1994-12**Valid until**  
2020-09-03

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Document-No.: **39.05.003**  
Revision-No.: **23**  
Effective Date: **Last date of signature**  
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Melsungen, 2015-09-03

i. V.



Thomas Stefan Brand  
Vice President Quality Management for non-active Medical  
Devices

Melsungen, 2015-09-03

i. V.



Ulrich Jedelhauser  
Senior Manager Regulatory Affairs CoE IV-Systems/  
IV-Access

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<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
0009483H	Original Perfusor® Line	IIa
0066086H	Original Perfusor® Line	IIa
0066087J	Original Perfusor® Line	IIa
0066088K	Original Perfusor® Line	IIa
0085882A	Original Perfusor® Leitung	IIa
0086547Y	Sistema para perfusão/Système de perfusion	IIa
0086789H	Sistema para perfusão/Système de perfusion	IIa
411402	Sistema para perfusão/Système de perfusion	IIa
8250146	Original Perfusor® Line	IIa
8255059	Original Perfusor® Line	IIa
8255067	Original Perfusor® Line	IIa
8255172	Original Perfusor® Line	IIa
8255253	Original Perfusor® Line	IIa
8255490	Original Perfusor® Line	IIa
8255504	Original Perfusor®-Leitung Typ: MR	IIa
8255504N	Original Perfusor® Line	IIa
8255563	Original Perfusor® Leitung	IIa
8272565	Original Perfusor® Line	IIa
8722820	Original Perfusor® Line	IIa
8722862	Original Perfusor® Line	IIa
8722862-20	Original Perfusor® Line	IIa
8722870	Original Perfusor®-Leitung Typ: MR	IIa
8722870N	Original Perfusor® Line	IIa
8722889	Original Perfusor®-Leitung Typ: MK	IIa
8722919	Original Perfusor® Line	IIa
8722919-20	Original Perfusor® Line	IIa
8722919TR	Original Perfusor®-Leitung	IIa
8722935	Original Perfusor® Line	IIa
8722935-20	Original Perfusor® Line	IIa
8722940	Original Perfusor® Line	IIa
8722941	Original Perfusor® Line	IIa
8722960	Original Perfusor® Line	IIa
8722960-20	Original Perfusor® Line	IIa
8722960TR	Original Perfusor®-Leitung	IIa
8723001	Original Perfusor® Line	IIa
8723010	Original Perfusor® Line	IIa

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<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
8723017	Original Perfusor® Line	Ila
8723017-20	Original Perfusor® Line	Ila
8723018	Original Perfusor® Line	Ila
8723060	Original Perfusor® Line	Ila
8723060-20	Original Perfusor® Line	Ila
8724032	Infusions-Leitung PE	Ila
8724415	Infusionsleitung PE	Ila
8726019	Original-Perfusor® Leitung PCA	Ila
8745641	Original Perfusor® Tubing PE	Ila
8745919	Original Perfusor®-Leitung Typ: MR	Ila
8745919N	Original Perfusor® Line	Ila
8750645	Original Perfusor® Line	Ila