

**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**Kundenspezifische Sets**  
(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  
Ridlerstraße 65  
80339 München  
Deutschland  
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**  
1995-06**Gültig bis**  
2024-05-26hereby declare in our own responsibility  
that the product/s**Customized Kits**  
(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  
Ridlerstraße 65  
80339 München  
Germany  
Identification number 0123**Date of first CE-marking**  
1995-06**Valid until**  
2024-05-26

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4088786	ProSet Spritzen-Set	Ila
4182813	ProSet Spritzen-Set	Ila
4182814	ProSet Infusions - Set	Ila
4185498	ProSet Infusionset (Herz OP)	Ila
4185633	ProSet Set Equipo Perfusor® 20 ml	Ila
4187903	ProSet Perfusor® Spritzen-Set	Ila
4187915	ProSet Perfusor® Spritzen Set	Ila

### Amendment Information

Version	Description of the changes
12	Change product name of art. no. 4182814
13	Add art. no. 4182815
14	Delete art. no. 4182815 (will be covered by 39.05.001KIT)
15	Add art. no. 4187015
16	Correct art. no. from 4187015 to 4187915

Title: Declaration of Conformity - 39.05.019KIT - Original Perfusor Syringe ProSet 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: Wednesday, 07 October 2020, 08:24 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Seidel, Stefan (seidstde)  
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems  
Date: Wednesday, 07 October 2020, 09:44 W. Europe Daylight Time  
Meaning: Approve Document

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UserName: Brand, Thomas (brantode)  
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices  
Date: Thursday, 08 October 2020, 09:30 W. Europe Daylight Time  
Meaning: Approve Document

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