

**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**Safeflow,  
Safeflow Extension Set,  
Safeflow Y-Extension Set,  
Safsite®**

Sicherheitskonnektoren für Infusionssysteme

(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**Safsite 1994-12  
Safeflow 2006-06hereby declare in our own responsibility  
that the product/s**Safeflow,  
Safeflow Extension Set,  
Safeflow Y-Extension Set,  
Safsite®**

Safety connectors for infusion systems

(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**Safsite 1994-12  
Safeflow 2006-06

**Gültig bis**  
2024-05-26

**Valid until**  
2024-05-26

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
409100H	Safeflow	Ila
409100CN	Safeflow	Ila
409101H	Safeflow	Ila
409110H	Safeflow	Ila
4091000	Safsite®	Ila
4097145	Safeflow Y-Extension Set	Ila
4097145N	Safeflow Extension Set	Ila
4097148	Safeflow Y-Extension Set	Ila
4097148N	Safeflow Extension Set	Ila
4097154	Safeflow Extension Set	Ila
4097154N	Safeflow Extension Set	Ila

**Amendment Information**

<b>Version</b>	<b>Description of the changes</b>
13	Delete Out of Market Article no. 4091019
14	Add art. no. 4097145N, 4097154N
15	Add art. no. 4097148N
16	Update validity

Title: Declaration of Conformity - 39.05.015 - Safeflow 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: Seidel, Stefan (seidstde)  
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Meaning: Approve Document

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UserName: Brand, Thomas (brantode)  
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