

**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 14th 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

Effective



**- Conformity Declaration -
Declaration of Conformity -
39.05.015 - Safeflow**

B. Braun Melsungen AG
IV Systems - Regulatory Affairs

Document No.: 39.05.015

Version: 16.0

Effective Date: 2020-03-30

Page: 2 of 5

Gültig bis
2024-05-26

Valid until
2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
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

Version	Description of the changes
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:

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