

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/übereinstimmen

Richtlinie 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

2024-05-26

hereby 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 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

1995-06

Valid until

2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4097146	ProSet Safeflow Extension Set	Ila
4097147	ProSet Safeflow Extension Set	Ila

Amendment Information

Version	Description of changes
03.0	Add art. no. 4094612
04.0	Update validity
05.0	Delete art. no. 4094612 (covered by DoC 39.05.023KIT) Add art. no. 4097146, 4097147

Title: Declaration of Conformity - 39.05.015KIT - Safeflow ProSet 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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Meaning: Document signed as Author

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Meaning: Approve Document

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Meaning: Approve Document
