

Konformitätserklärung Declaration of Conformity

Wir

We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

erklären in eigener Verantwortung,
dass das Produkt

hereby declare in our own responsibility
that the product

Kundenspezifische Sets
(Artikelnummern siehe Anlage I)

Customized Kits
(article numbers see attachment I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

is/are in compliance with the following directive

Richtlinie 93/42/EWG des Rates vom 14. Juni
1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

Council Directive 93/42/EEC of 14th June
1993
concerning Medical Devices
amended by Directive 2007/47/EC

Konformitätsbewertungsverfahren
nach Anhang VII und V
der oben genannten Richtlinie

Conformity Assessment Procedure
according to annex VII and V
of the Council Directive named above

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse I steril

Classification
according to annex IX of the
Council Directive named above
Class I sterile

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123

Notified Body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Datum der ersten CE-Kennzeichnung
1994-12

Date of first CE-marking
1994-12

Gültig bis
2024-05-26

Valid until
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
A1664	Koppel-System	I steril / I sterile
GN094	Einmalschlauchset für Spülsystem / single use tubing set for irrigation system	I steril / I sterile

Amendment Information

Version	Description of the changes
12	Add art. no. 4087193
13	Delete out of market article no. S71514
14	Delete art. no. 4087193 (will be covered by 39.05.001KIT)
15	Update validity

Title: Declaration of Conformity - 39.05.014KIT - Ecoflac Transofix 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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Date: Tuesday, 28 April 2020, 17:57 W. Europe Daylight Time
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Meaning: Approve Document
