

**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**Ecoflac® Mix**

Transferkappe für sterile Flüssigkeiten

Ecoflac® Connect

Transferset, geschlossenes System

Transofix®

Überleitungsset

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni
1993über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang VII und V
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse I steril**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**

Ecoflac® Mix	2007-06
Transofix®	2007-06
Ecoflac® Connect	2009-06

hereby declare in our own responsibility
that the product/s**Ecoflac® Mix**

Transfer cap for sterile fluids

Ecoflac® Connect

Transfer set, closed system

Transofix®

Fluid transfer set

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June
1993concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according to annex VII and V
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class I sterile**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Date of first CE-marking**

Ecoflac® Mix	2007-06
Transofix®	2007-06
Ecoflac® Connect	2009-06

Gültig bis
2024-05-26

Valid until
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
16401	Ecoflac® Mix	I steril / I sterile
16401IN	Ecoflac® Mix	I steril / I sterile
4090500	Transofix®	I steril / I sterile
4090500IN	Transofix®	I steril / I sterile
4090549	Ecoflac® Connect	I steril / I sterile
4090550	Ecoflac® Connect	I steril / I sterile
4090552	Ecoflac® Connect	I steril / I sterile

Amendment Information

Version	Description of the changes
16	Delete out of market art. no. 0043066L, 0064500J, 0059572C, 0057124S, 15093, 3975002, 0005618G, 0005619H, 0005620J, 0065203Y
17	Add art. no. 4090500IN
18	Delete out of market art. no. 0043070R
19	Add art. no. 16401IN
20	Delete out of market art. no. 4089510, 0010724G, 0011243W, 0044834H

Title: Declaration of Conformity - 39.05.014 - Ecoflac Transofix 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, 18 June 2019, 08:38 W. Europe Daylight Time
Meaning: Approve Document

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Meaning: Approve Document
