

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®

Überleitungssset

(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 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
1993

concerning 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

Effective



**- Conformity Declaration -
Declaration of Conformity -
39.05.014 - Ecoflac Transofix**

B. Braun Melsungen AG
IV Systems - Regulatory Affairs

Document No.: 39.05.014

Version: 20.0

Effective Date: 2019-06-21

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
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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Title: Administrator Regulatory Affairs
Date: Monday, 17 June 2019, 15:33 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Brand, Thomas (brantode)
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Meaning: Approve Document
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