

**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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Title: Administrator Regulatory Affairs
Date: Monday, 17 June 2019, 15:33 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Tuesday, 18 June 2019, 08:38 W. Europe Daylight Time
Meaning: Approve Document

UserName: Seidel, Stefan (seidstde)
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Date: Friday, 21 June 2019, 10:34 W. Europe Daylight Time
Meaning: Approve Document
