

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201**erklären in eigener Verantwortung,
dass die Produkte**Ecoflac® Connect****Überleitgerät für nichttoxische Flüssigkeiten
in Einzeldosen mit Ecoflac® plus-Behälter.
Geschlossenes System**Basis UDI-DI: 403923900000027324
(Artikelnummern siehe Anlage I)mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 übereinstimmen**Konformitätsbewertungsverfahren**
nach Anhang IX
der oben genannten Verordnung**Klassifizierung**
gemäß Anhang VIII der oben genannten
Verordnung
Klasse I steril**Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**
gemäß gültigem EU Zertifikat
(G11 012974 0626)hereby declare in our sole responsibility
that the products**Ecoflac® Connect****Transfer device for single dose, non-toxic
fluids with Ecoflac® plus container. Closed
System**Basic UDI-DI: 403923900000027324
(article numbers see attachment I)are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745**Conformity Assessment Procedure**
according to annex IX
of the Regulation named above**Classification**
according to annex VIII of the Regulation named
above
Class I sterile**Notified Body**
TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**
according to our valid EU Certificate
(G11 012974 0626)

Anlage I / Attachment I

Basic UDI-DI 403923900000027324

| Art.-Nr. / Art. No. | Produktname / Product name |
|----------------------------|-----------------------------------|
|----------------------------|-----------------------------------|

| | |
|---------|------------------|
| 4090549 | Ecoflac® Connect |
|---------|------------------|

| | |
|---------|------------------|
| 4090550 | Ecoflac® Connect |
|---------|------------------|

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| 4090552 | Ecoflac® Connect |
|---------|------------------|

| Klasse / Class |
|-----------------------|
|-----------------------|

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| I steril / I sterile |
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|----------------------|
| I steril / I sterile |
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| I steril / I sterile |
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Document amendment information

| Version | Description of the changes |
|---------|--|
| 1.0 | Initial Version under 2017/745 MDR based on change HC-CHC-M-DIV-2589 |

Title: Declaration of Conformity - 214-007-MDR - Ecoflac Connect Initiator: Susanne ? Olbricht

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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