

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-00000201**erklären in eigener Verantwortung,
dass das Produkt**Ecoflac® Mix**

Transfer-Kappe für sterile Flüssigkeiten

Basis UDI-DI: 403923900000027222
(Artikelnummern siehe Anlage I)mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 übereinstimmt**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 product**Ecoflac® Mix**

Transfer cap for sterile fluids

Basis UDI-DI: 403923900000027222
(article numbers see attachment I)is 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 40392390000027222****Art.-Nr. / Art. No. Produktname / Product name**
16401N Ecoflac® Mix**Klasse / Class**
I steril / I sterile

Document amendment information

| Version | Description of the changes |
|---------|------------------------------------|
| 1.0 | Initial Version under 2017/745 MDR |

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