

**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 das/die Produkt/e**Transofix®**Transferset für sterile Flüssigkeiten
(Artikelnummern und Basic UDI-DI siehe Anlage I)mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/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
(Nr. G11 012974 0626)hereby declare in our own responsibility
that the product/s**Transofix®**Transfer set for sterile fluids
(article numbers and Basic UDI-DI see attachment I)is/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
(No. G11 012974 0626)

Anlage I / Attachment I

Basic UDI-DI: 4039239000000271ZV

Art.-Nr. / Art. No.	Produktname / Product name
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4090500	Transofix®
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4090500IN	Transofix®
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Klasse / Class

I steril / I sterile

I steril / I sterile

Document amendment information

Version	Description of the changes
1.0	Initial Version under MDR

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