

**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**Transofix®**Transferset für sterile Flüssigkeiten
Basis UDI-DI: 4039239000000271ZV
(Artikelnummern und Basic UDI-DI 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
(Nr. G11 012974 0626)hereby declare in our own responsibility
that the products**Transofix®**Transfer set for sterile fluids
Basic UDI-DI: 4039239000000271ZV
(article numbers and Basic UDI-DI 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
(No. G11 012974 0626)

Effective

Anlage I / Attachment I**Basic UDI-DI: 4039239000000271ZV**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4090500	Transofix®	I steril / I sterile
4090500IN	Transofix®	I steril / I sterile
4090501	Transofix®	I steril / I sterile
4090501BR	Transofix®	I steril / I sterile
4090501IN	Transofix®	I steril / I sterile
4090501PE	Transofix®	I steril / I sterile

Effective

Document amendment information

Version	Description of the changes
1.0	Initial Version under MDR
2.0	Addition of article no. 4090501, 4090501BR, 4090501IN, and 4090501PE based on project ACTIVE F3 (with corresponding change controls HC-CHC-M-DIV-2459 and HC-CHC-M-DIV-2537). Minor editorial adaptations.

Title: Declaration of Conformity - 214-006 - Transofix MDR Initiator: Jascha T Manschwetus

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

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