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)

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

Effective

Document amendment information

Version	Description of the changes
1.0	Initial Version under MDR

Title: Declaration of Conformity - 214-006 - Transofix MDR 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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