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

Intrafix® Air
Intrafix® Primeline
Intrafix® SafeSet
Infusionsgeräte zur Infusion mit
Schwerkraft sowie mit geeigneten Pumpen.

(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 IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis
gemäß gültigem EU Zertifikat
(Nr. G10 012974 0611)

hereby declare in our own responsibility
that the product/s

Intrafix® Air
Intrafix® Primeline
Intrafix® SafeSet
I.V. administration sets for infusion by gravity
and compatible pumps

(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 IIa

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Valid until
according to our valid EU Certificate
(No. G10 012974 0611)

Effective

Anlage I / Attachment I

Basic UDI-DI 40392390000007812U

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4060369L	Intrafix® Primeline	IIa
4060407	Intrafix® Primeline	IIa
4062158	Intrafix® Primeline	IIa
4062158C	Intrafix® Primeline	IIa
4062182	Intrafix® Primeline	IIa
4062955	Intrafix® Air	IIa
4062957E	Intrafix® Primeline	IIa
4062981L	Intrafix® Primeline	IIa
4062982L	Intrafix® Primeline	IIa
4062983L	Intrafix® Primeline	IIa
4063000	Intrafix® SafeSet	IIa
4063001	Intrafix® SafeSet	IIa
4063003	Intrafix® SafeSet	IIa
4063004	Intrafix® SafeSet	IIa
4063004C	Intrafix® SafeSet	IIa
4063004M	Intrafix® SafeSet	IIa
4063005	Intrafix® SafeSet	IIa
4063144	Intrafix® SafeSet	IIa
4063148	Intrafix® SafeSet	IIa
4063287	Intrafix® Primeline	IIa
4110000	Intrafix® SafeSet	IIa
4110010	Intrafix® SafeSet	IIa

Basic UDI-DI 40392390000014832Q

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4062877	Intrafix® Primeline	IIa
4062878	Intrafix® SafeSet	IIa
4110001	Intrafix® Primeline	IIa
4110002	Intrafix® Primeline	IIa

Effective

Basic UDI-DI 40392390000014822N

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4060563	Intrafix® Primeline	IIa

Effective

Document amendment information

Version	Description of the changes
1.0	First issue under Medical Device Regulation (MDR)

Effective

Title: Declaration of Conformity - 102-001 - MDR - Intrafix P. Initiator: Meike ? Junius

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

UserName: Junius, Meike (junimede)
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UserName: Brand, Thomas (brantode)
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Meaning: Approve Document
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