

**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)

Anlage I / Attachment I**Basic UDI-DI 40392390000007812U**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4060369L	Intrafix® Primeline	Ila
4060407	Intrafix® Primeline	Ila
4062158	Intrafix® Primeline	Ila
4062158C	Intrafix® Primeline	Ila
4062182	Intrafix® Primeline	Ila
4062955	Intrafix® Air	Ila
4062957E	Intrafix® Primeline	Ila
4062981L	Intrafix® Primeline	Ila
4062982L	Intrafix® Primeline	Ila
4062983L	Intrafix® Primeline	Ila
4063000	Intrafix® SafeSet	Ila
4063001	Intrafix® SafeSet	Ila
4063003	Intrafix® SafeSet	Ila
4063004	Intrafix® SafeSet	Ila
4063004C	Intrafix® SafeSet	Ila
4063004M	Intrafix® SafeSet	Ila
4063005	Intrafix® SafeSet	Ila
4063006	Intrafix® SafeSet	Ila
4063144	Intrafix® SafeSet	Ila
4063148	Intrafix® SafeSet	Ila
4063287	Intrafix® Primeline	Ila
4110000	Intrafix® SafeSet	Ila
4110010	Intrafix® SafeSet	Ila

Basic UDI-DI 40392390000014832Q

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

Effective

Basic UDI-DI 40392390000014832Q

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4110002	Intrafix® Primeline	Ila

Basic UDI-DI 40392390000014822N

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

Document amendment information

Version	Description of the changes
1.0	First issue under Medical Device Regulation (MDR)
2.0	Addition of art. no. 4063006

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:

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