

**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® Primeline
Intrafix® SafeSet
Intrapur® Inline**

Infusionsgeräte für Schwerkraftinfusionen.

(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**Intrafix® Primeline
Intrafix® SafeSet
Intrapur® Inline**

I.V. administration sets for gravity infusion

(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 40392390000026525**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4052480	Intrafix® Primeline	I steril / I sterile
4060369	Intrafix® Primeline	I steril / I sterile
4062181	Intrafix® Primeline	I steril / I sterile
4062191	Intrafix® Primeline	I steril / I sterile
4063002	Intrafix® SafeSet	I steril / I sterile
4063007	Intrafix® SafeSet	I steril / I sterile
4063008	Intrafix® SafeSet	I steril / I sterile
4063009	Intrafix® SafeSet	I steril / I sterile
4063020	Intrafix® SafeSet	I steril / I sterile
4063100	Intrafix® SafeSet	I steril / I sterile
4064007	Intrafix® Primeline	I steril / I sterile
4064008	Intrafix® Primeline	I steril / I sterile
4064009	Intrafix® Primeline	I steril / I sterile
4064100	Intrafix® Primeline	I steril / I sterile
4099842N	Intrapur® Inline	I steril / I sterile
4110020	Intrafix® SafeSet	I steril / I sterile

Basic UDI-DI 40392390000014812L

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
0086774R	Intrafix® Primeline	I steril / I sterile
4063131	Intrafix® SafeSet	I steril / I sterile

Document amendment information

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

Title: Declaration of Conformity - 100-001 - MDR - Intrafix G 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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