

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

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

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 4039239000007822W

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4063000A	SafeSet	Ila
4063001CN	SafeSet	Ila
4063003CN	SafeSet	Ila
4063004CN	SafeSet	Ila
4063004SFCN	SafeSet	Ila
4063005CN	SafeSet	Ila
4063006CN	SafeSet	Ila

Document amendment information

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

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