

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
DE-MF-000000201**erklären in eigener Verantwortung,
dass das/die Produkt/e**Safeflow**

Nadelfreie Injektion/ Infusionsventil

Safeflow Extension SetVerlängerungsset mit kleinem Durchmesser für
Infusionsleitungen.

(Artikelnummern und Basis 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**Safeflow**

Needlefree Injection / Infusion-Valve

Safeflow Extension Set

Smallbore extension set for infusion lines.

(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 4039239000008162N**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
409110H	Safeflow	Ila
409100CN	Safeflow	Ila
409101H	Safeflow	Ila
409100H	Safeflow	Ila

Basic UDI-DI 4039239000008152L

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4097154N	Safeflow Extension Set	Ila
4097145N	Safeflow Extension Set	Ila
4097154	Safeflow Extension Set	Ila

Basic UDI-DI 40392390000027222S

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4097148N	Safeflow Extension Set	Ila

Document amendment information

Version	Description of the changes
1.0	Initial version.

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