

**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

hereby declare in our own responsibility
that the product/s

Safeflow

Nadelfreie Injektion/ Infusionsventil

Safeflow

Needlefree Injection / Infusion-Valve

Safeflow Extension Set

Verlängerungsset mit kleinem Durchmesser für
Infusionsleitungen.

Safeflow Extension Set

Smallbore extension set for infusion lines.

(Artikelnummern und Basis UDI-DI siehe Anlage I)

(article numbers and Basic UDI-DI see attachment I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/übereinstimmen

is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Conformity Assessment Procedure
according to annex IX
of the Regulation named above

Klassifizierung
gemäß Anhang VIII der oben genannten
Verordnung
Klasse IIa

Classification
according to annex VIII of the Regulation named
above
Class IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

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

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

Effective

Anlage I / Attachment I**Basic UDI-DI 40392390000008162N**

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

Basic UDI-DI 40392390000008152L

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 403923900000027222S

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.

Title: Declaration of Conformity - 119-001 - MDR - Safety Connectors Initiator: Daniela ? Schul

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

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Meaning: Document signed as Author

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Meaning: Approve Document

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Meaning: Approve Document

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