

**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**Extension Line**Zur Verlängerung von Infusions- und
Transfusionsleitungen.
Basis UDI-DI: 40392390000007893C

(Artikelnummern 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**Extension Line**

For extending infusion and transfusion lines.

Basic UDI-DI: 40392390000007893C

(article numbers 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 4039239000007893C**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4051807	Extension Line	Ila
4054393	Extension Line	Ila
4054394	Extension Line	Ila
4055137	Extension Line	Ila
4055138	Extension Line	Ila
4055139	Extension Line	Ila
4055140	Extension Line	Ila
4097572	Extension Line	Ila
9500049	Extension Line	Ila
9500057	Extension Line	Ila
9500065	Extension Line	Ila

Document amendment information

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

Title: Declaration of Conformity - 114-005 - MDR - Extension Lines Initiator: Meike ? Junius

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

UserName: Junius, Meike (junimede)
Title: Manager Regulatory Affairs CoE Infusion & Pain Therapy
Date: Tuesday, 21 May 2024, 13:03 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Tuesday, 21 May 2024, 15:38 W. Europe Daylight Time
Meaning: Approve Document

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Tuesday, 21 May 2024, 18:41 W. Europe Daylight Time
Meaning: Approve Document
