

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, Type: Heidelberger
Heidelberger Extension Tubing**

Zur Verlängerung von Infusions- und
Transfusionsleitungen.

Basis UDI-DI: 403923900000078636

Heidelberger Extension Tubing

Zur Verlängerung von Infusionsleitungen.

Basis UDI-DI: 40392390000026953G

(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, Type: Heidelberger
Heidelberger Extension Tubing**

For extending infusion and transfusion lines.

Basic UDI-DI: 403923900000078636

Heidelberger Extension Tubing

For extending infusion lines.

Basic UDI-DI: 40392390000026953G

(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 40392390000078636

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4033809	Heidelberg Extension Tubing	IIa
4034589	Heidelberg Extension Tubing	IIa
4038703	Heidelberg Extension Tubing	IIa
4055128	Heidelberg Extension Tubing	IIa
4055136	Heidelberg Extension Tubing	IIa
4097130	Extension Line, Type: Heidelberg	IIa
4097173	Extension Line, Type: Heidelberg	IIa
4097190	Extension Line, Type: Heidelberg	IIa
4097262	Extension Line, Type: Heidelberg	IIa
4097290	Extension Line, Type: Heidelberg	IIa
4097291	Extension Line, Type: Heidelberg	IIa
4097300	Extension Line, Type: Heidelberg	IIa
4097408	Extension Line, Type: Heidelberg	IIa

Basic UDI-DI 40392390000026953G

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4052145	Heidelberg Extension Tubing	IIa
4052197	Heidelberg Extension Tubing	IIa
4052197H	Heidelberg Extension Tubing	IIa

Document amendment information

Version	Description of the changes
1.0	First issue under Medical Device Regulation (MDR)
2.0	Correction of Basic UDI-DI from 4039239000007812U to 40392390000078636 and from 40392390000014832Q to 40392390000026953G in Attachment I.

Title: Declaration of Conformity - 114-001 - MDR - Extension Line Type Heidelberger 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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Meaning: Document signed as Author

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Date: Tuesday, 16 July 2024, 20:35 W. Europe Daylight Time
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Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 17 July 2024, 13:06 W. Europe Daylight Time
Meaning: Approve Document
