

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: Alargadera
In-line injection tubing
Double Spike Adaptor

Zur Verlängerung von Infusions- und
Transfusionsleitungen.

Basis UDI-DI: 40392390000007883A

LS-2 Connector
LS-3 Connector
LS-4 Connector
LS-5 Connector

Original-Kucher-extension tubing
Leitungsverbinder

Basis UDI-DI: 403923900000078738

(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

hereby declare in our own responsibility
that the product/s

Extension Line, Type: Alargadera
In-line injection tubing
Double Spike Adaptor

For extending infusion and transfusion lines.

Basic UDI-DI: 40392390000007883A

LS-2 Connector
LS-3 Connector
LS-4 Connector
LS-5 Connector

Original-Kucher-extension tubing
Tube Connectors

Basic UDI-DI: 403923900000078738

(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

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

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

Anlage I / Attachment I**Basic UDI-DI 4039239000007883A**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4054032	Double Spike Adaptor	Ila
4094603	Extension Line, Type: Alargadera	Ila
4247116	In-line injection tubing	Ila

Basic UDI-DI 40392390000078738

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4053753	LS-3 Connector	Ila
4097122	LS-2 Connector	Ila
4097149	LS-4 Connector	Ila
4097157	LS-5 Connector	Ila
4887441	Original-Kucher-extension tubing	Ila
9500103	LS-2 Connector	Ila

Document amendment information

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

Title: Declaration of Conformity - 114-002 - MDR - Connectors and Connection Tubings 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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