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 die Produkte

hereby declare in our own responsibility that the products

Original Perfusor® Syringe 20 ml
Original Perfusor® Syringe 50 ml
3-piece Single-use syringe with Luer Lock connector for usage with compatible pumps for Infusion Therapy
Basis UDI-DI: 403923900000077939
(Artikelnummern siehe Anlage I)

Original Perfusor® Syringe 20 ml
Original Perfusor® Syringe 50 ml
3-piece Single-use syringe with Luer Lock connector for usage with compatible pumps for Infusion Therapy
Basic UDI-DI: 403923900000077939
(article numbers see attachment I)

Original Perfusor® Syringe 20 ml
Original Perfusor® Syringe 50 ml
single-use syringes, 3-piece, for usage with compatible pumps
Basis UDI-DI: 40392390000029923R
(Artikelnummern siehe Anlage I)

Original Perfusor® Syringe 20 ml
Original Perfusor® Syringe 50 ml
single-use syringes, 3-piece, for usage with compatible pumps
Basic UDI-DI: 40392390000029923R
(article numbers see attachment I)

Original Perfusor® Syringe 50 ml
3-piece Single-use syringe with Luer Lock connector for usage with compatible pumps for lightsensitive medicaments for Infusion Therapy Type UV-Protect
Basis UDI-DI: 403923900000207124
(Artikelnummern siehe Anlage I)

Original Perfusor® Syringe 50 ml
3-piece Single-use syringe with Luer Lock connector for usage with compatible pumps for lightsensitive medicaments for Infusion Therapy Type UV-Protect
Basic UDI-DI: 403923900000207124
(article numbers see attachment I)

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

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

Effective

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

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

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

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

Effective

Anlage I / Attachment I

Basic UDI-DI 403923900000077939

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8728615	Original Perfusor® Syringe 20 ml	IIa
8728615C	Original Perfusor® Syringe 20 ml	IIa
8728844F-04	Original Perfusor® Syringe 50 ml	IIa
8728844F-06	Original Perfusor® Syringe 50 ml	IIa
8728844F-20	Original Perfusor® Syringe 50 ml	IIa

Basic UDI-DI 40392390000029923R

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8728623	Original Perfusor® Syringe 20 ml	IIa
8728623C	Original Perfusor® Syringe 20 ml	IIa
8728810F-04	Original Perfusor® Syringe 50 ml	IIa
8728810F-06	Original Perfusor® Syringe 50 ml	IIa
8728810F-20	Original Perfusor® Syringe 50 ml	IIa
8728852F-04	Original Perfusor® Syringe 50 ml	IIa
8728852F-06	Original Perfusor® Syringe 50 ml	IIa
8728852F-20	Original Perfusor® Syringe 50 ml	IIa

Basic UDI-DI 403923900000207124

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8728861F-04	Original Perfusor® Syringe 50 ml	IIa
8728861F-06	Original Perfusor® Syringe 50 ml	IIa
8728861F-20	Original Perfusor® Syringe 50 ml	IIa

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Document amendment information

Version	Description of the changes
2.0	Addition of article no. 8728623 and 8728623C based on MDR conversion project S.101-0470.01 (change control HC-CHC-M-DIV-2190). Addition of article codes 8728844F-04, 8728844F-06, 8728844F-20, 8728852F-04, 8728852F-06, 8728852F-20, 8728810F-04, 8728810F-06 and 8728810F-20 based in change control HC-CHC-M-DIV-2587. Addition of Basic UDI-DI: 403923900000207124 with article codes 8728861F-04, 8728861F-06 and 8728861F-20 based on change control HC-CHC-M-DIV-2587.
1.0	Initial Version under Medical Device Regulation (EU) 2017/745.

Title: Declaration of Conformity - 160-001 - MDR - Original Perfusor Syringes Initiator: Julia2 ? Mueller

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

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