

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

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

single-use syringes, 3-piece, for usage with
compatible pumps

Basis UDI-DI: 403923900000029923R
(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

Basis UDI-DI: 4039239000000207124
(Artikelnummern siehe Anlage I)

Original Perfusor® Syringe 50 ml

Single-use syringes, 3-piece, for usage with
compatible pumps, for light-sensitive
medicaments, 50ml scale

Basis UDI-DI: 403923900000030742H
(Artikelnummern siehe Anlage I)

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

hereby declare in our own responsibility
that the products

Original Perfusor® Syringe 20 ml
Original Perfusor® Syringe 50 ml

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Basic UDI-DI: 403923900000077939
(article numbers see attachment I)

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Original Perfusor® Syringe 50 ml

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(article numbers see attachment I)

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Basic UDI-DI: 4039239000000207124
(article numbers see attachment I)

Original Perfusor® Syringe 50 ml

Single-use syringes, 3-piece, for usage with
compatible pumps, for light-sensitive
medicaments, 50ml scale

Basis UDI-DI: 403923900000030742H
(article numbers see attachment I)

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

Effective

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)

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 403923900000077939**

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

Basic UDI-DI 403923900000029923R

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

Basic UDI-DI 4039239000000207124

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

Basic UDI-DI 403923900000030742H

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8728862F-06	Original Perfusor® Syringe 50 ml	Ila

Document amendment information

Version	Description of the changes
3.0	Addition of article code 8728862F-06 based on project S.276-24AJ.01
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: Katharina Berlinecke

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

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