

Konformitätserklärung Declaration of Conformity

Wir

We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

erklären in eigener Verantwortung,
dass das/die Produkt/e

hereby declare in our own responsibility
that the product/s

Aspirationskanüle
Aspirationskanüle

Aspirationskanüle
Aspiration Needle

Original Perfusor® Syringe 20 ml,
Original Perfusor® Syringe 50 ml,
Original-Perfusor®- Syringe 50 ml
Original Perfusor® Spritze

Original Perfusor® Syringe 20 ml,
Original Perfusor® Syringe 50 ml,
Original-Perfusor®- Syringe 50 ml
Original Perfusor® Syringe

Set Equipo Perfusor®
Original Perfusor® Spritze 50 ml mit
Aspirationskanüle und 150 cm PE
Perfusorleitung
(Artikelnummern siehe Anlage I)

Set Equipo Perfusor®
Original Perfusor® Syringe 50 ml with
aspiration needle and 150 cm PE Perfusor
tubing
(article numbers see attachment I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

is/are in compliance with the following directive

Richtlinie 93/42/EWG des Rates vom 14. Juni
1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4)
nach Anhang VII und V
der oben genannten Richtlinie

Conformity Assessment Procedure
according to annex II (excluding section 4)
according to annex VII and V
of the Council Directive named above

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa
Klasse I steril

Classification
according to annex IX of the
Council Directive named above
Class IIa
Class I sterile

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München

Notified Body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München

Deutschland
Kennnummer 0123

Datum der ersten CE-Kennzeichnung
1995-06

Gültig bis
2024-05-26

Germany
Identification number 0123

Date of first CE-marking
1995-06

Valid until
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
16417F	Set Equipo Perfusor®	Ila
8258813	Aspirationskanüle	I steril / I sterile
8258821	Aspirationskanüle	I steril / I sterile
8728615	Original Perfusor® Syringe 20 ml	Ila
8728615C	Original Perfusor® Syringe 20 ml	Ila
8728623	Original Perfusor® Syringe 20 ml	Ila
8728623C	Original Perfusor® Syringe 20 ml	Ila
8728800F	Original Perfusor® Syringe 50 ml	Ila
8728801F	Original Perfusor® Syringe 50 ml	Ila
8728810F	Original Perfusor® Syringe 50 ml	Ila
8728828F	Original Perfusor® Syringe 50 ml	Ila
8728836F	Original-Perfusor®- Syringe 50 ml	Ila
8728844F	Original Perfusor® Syringe 50 ml	Ila
8728852F	Original Perfusor® Syringe 50 ml	Ila
8728861F-04	Original Perfusor® Syringe 50 ml	Ila
8728861F-06	Original Perfusor® Syringe 50 ml	Ila
8728861F-20	Original Perfusor® Syringe 50 ml	Ila
8728801F-20	Original Perfusor® Syringe 50 ml	Ila
8728810F-20	Original Perfusor® Syringe 50 ml	Ila
8728844F-20	Original Perfusor® Syringe 50 ml	Ila
8728852F-20	Original Perfusor® Syringe 50 ml	Ila
8728801F-04	Original Perfusor® Syringe 50 ml	Ila
8728810F-04	Original Perfusor® Syringe 50 ml	Ila
8728844F-04	Original Perfusor® Syringe 50 ml	Ila
8728852F-04	Original Perfusor® Syringe 50 ml	Ila
8728801F-06	Original Perfusor® Syringe 50 ml	Ila
8728810F-06	Original Perfusor® Syringe 50 ml	Ila
8728844F-06	Original Perfusor® Syringe 50 ml	Ila
8728852F-06	Original Perfusor® Syringe 50 ml	Ila

Amendment Information

Version	Description of the changes
14	Add art. no. 8728615C, 8728623C
15	Add art. no. 8728801F-20, 8728810F-20, 8728844F-20, 8728852F-20, 8728801F-04, 8728810F-04, 8728844F-04, 8728852F-04, 8728801F-06, 8728810F-06, 8728844F-06, 8728852F-06
16	Update validity

Title: Declaration of Conformity - 39.05.019 - Original Perfusor Syringe Initiator: Caroline ? Herbst

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

UserName: Herbst, Caroline (fuehcade)
Title: Administrator Regulatory Affairs
Date: Monday, 30 March 2020, 11:53 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Brand, Thomas (brantode)
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Date: Monday, 30 March 2020, 18:58 W. Europe Daylight Time
Meaning: Approve Document
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