

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

Aspirationskanüle
Aspirationskanüle

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

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

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

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

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

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

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123

hereby declare in our own responsibility
that the product/s

Aspirationskanüle
Aspiration Needle

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

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

is/are in compliance with the following directive

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

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

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

Notified Body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Konformitätserklärung
Declaration of ConformityDocument-No.: **39.05.019**Revision-No.: **15**Effective Date: **Last date of signature**Page: **2 of 3****Datum der ersten CE-Kennzeichnung**

1995-06

Gültig bis

2021-12-22

Date of first CE-marking

1995-06

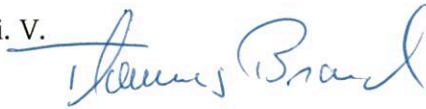
Valid until

2021-12-22

Melsungen, 2016-12-22

B. Braun Melsungen AG

i. V.



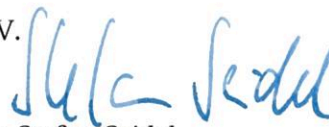
Thomas Stefan Brand

Vice President Quality Management for non-active Medical Devices

Melsungen, 2016-12-22

B. Braun Melsungen AG

i. V.



Dr. Stefan Seidel

Head of Regulatory Affairs CoE IV-Systems

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signature**Page: **3 of 3****Anlage I / Attachment I**

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