

**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**Intrapur®,
Intrapur®-Neonat,
Intrapur®-Neonat Lipid
Infusionsfilter**

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni
1993über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**
1994-12**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Intrapur®,
Intrapur®-Neonat,
Intrapur®-Neonat Lipid
Infusion Filter**

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June
1993concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according to annex II (excluding section 4)
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class IIa**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Date of first CE-marking**
1994-12**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4093216	Intrapur®	Ila
4099451	Intrapur®-Neonat	Ila
4099460	Intrapur®-Neonat Lipid	Ila
4099702	Intrapur®	Ila
4099753	Intrapur®	Ila
4099800	Intrapur®	Ila
4099850	Intrapur®	Ila
4183916	Intrapur®	Ila
4185226	Intrapur®-Neonat	Ila

Amendment Information

Version	Description of the changes
14	Delete out of market article no. 4184386
15	Update validity

Title: Declaration of Conformity - 39.05.008 - Intrapur Initiator: Caroline ? Herbst

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

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Meaning: Document signed as Author

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Date: Monday, 30 March 2020, 14:16 W. Europe Daylight Time
Meaning: Approve Document

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Date: Monday, 30 March 2020, 18:46 W. Europe Daylight Time
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