

**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**Sangofix®,
Sangofix® B,
Sangofix® Air,
Sangopur®,
Y-Set**

Transfusionsgeräte mit und ohne Belüftung

(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**
1994-12hereby declare in our own responsibility
that the product/s**Sangofix®,
Sangofix® B,
Sangofix® Air,
Sangopur®,
Y-Set**Blood administration sets vented and non-
vented

(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

Effective

Gültig bis
2024-05-26

Valid until
2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
0086813H	Sangofix®	Ila
4034228	Sangofix®	Ila
4039785	Y-Set	Ila
4050151	Sangofix® Air	Ila
4050151SF	Sangofix® Air	Ila
4050192	Sangofix®	Ila
4050192H	Sangofix®	Ila
4050193	Sangofix®	Ila
4050193H	Sangofix®	Ila
4051718	Sangofix®	Ila
4051998	Sangofix®	Ila
4051998H	Sangofix®	Ila
4052005	Sangofix®	Ila
4052005H	Sangofix®	Ila
4052005SF	Sangofix®	Ila
4052013	Sangofix®	Ila
4052013H	Sangofix®	Ila
4052218	Sangofix®	Ila
4052218H	Sangofix®	Ila
4053710	Sangofix®	Ila
4053710H	Sangofix®	Ila
4053710SF	Sangofix®	Ila
4080187	Sangofix® Air	Ila
4100514	Sangofix®	Ila
4107411	Sangofix®	Ila
4108884	Sangofix®	Ila
4116011F	Sangofix®	Ila
4117301	Sangofix®	Ila
4117310	Sangofix® B	Ila
4117549	Sangofix®	Ila
4118219	Sangofix®	Ila
4146492	Sangofix®	Ila
4146581	Sangopur®	Ila

Amendment Information

Version	Description of changes
25.0	Add art. no. 4050151SF, 4052005SF, 4053710SF
26.0	Delete out of market art. no. 9291016
27.0	Delete out of market art. no. 4117522 Delete A25001 and A25001 (will be added to 39.05.007KIT)
28.0	Change Name of art. no. 4050151, 4050151SF and 4080187 from Sangofix® to Sangofix® Air Delete out of market art. no. 4117417F
29.0	Delete out of market art. no. 4053729, 4109112, 4117417U, 9291024

Title: Declaration of Conformity - 39.05.007 - Sangofix 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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