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

Kundenspezifische Sets
(Artikelnummern siehe Anlage I)

Customized Kits
(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) der oben genannten Richtlinie

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

Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie
Klasse IIa

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

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

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

Datum der ersten CE-Kennzeichnung
1994-12

Date of first CE-marking
1994-12

Gültig bis
2024-05-26

Valid until
2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
A25001	ProSet Sangofix®	IIa
A25002	ProSet Sangofix® 200µm	IIa
4050207	ProSet Sangopur® Anaesthetic Set	IIa
4117302	ProSet Sangofix® 150 cm, Luer Lock	IIa
4184750	ProSet Sangofix® B-Set	IIa
4186346	ProSet Sangofix®	IIa
4186532	ProSet Sangofix®	IIa
4186600	ProSet Sangofix®	IIa
4186601	PROSET WCS Sangofix® 200µm - PCV	IIa
4186602	PROSET WCS Sangofix® 200µm - PUR	IIa
4186603	ProSet Sangofix®	IIa
4186604	ProSet Sangofix®	IIa
4186606	ProSet Sangofix®	IIa
4186607	ProSet Sangofix®	IIa
4186608	ProSet Sangofix®	IIa
4186609	ProSet Sangofix®	IIa
4186610	ProSet Sangofix®	IIa

Effective

Amendment Information

Version	Description of changes
17.0	Change product name of art. no. A25001, A25002 from ” Transfusie-Systeem” to “ProSet Sangofix®”
18.0	Change product name of art. no. A25002 from “ProSet Sangofix®” to “ProSet Sangofix® 200µm”
19.0	Add art. no. 4186601, 4186602, 4186603, 4186604, 4186606, 4186607, 4186608, 4186609, 4186610
20.0	Delete out of market art. no. A2581
21.0	Change product name of art. no. 4186346 from “ProSet Special Paediatric Blood Administration” to “ProSet Sangofix®”

Title: Declaration of Conformity - 39.05.007KIT - Sangofix ProSet 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: Wednesday, 21 April 2021, 09:48 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Seidel, Stefan (seidstde)
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Date: Thursday, 22 April 2021, 15:07 W. Europe Daylight Time
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UserName: Brand, Thomas (brantode)
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Date: Thursday, 22 April 2021, 21:22 W. Europe Daylight Time
Meaning: Approve Document
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