

**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**Venofix® Safety**

Sicherheitsvenenpunktionsbesteck

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni
1993
über 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**
2012-07**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Venofix® Safety**

Safety winged IV needle

(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)
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**
2012-07**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4056501-01	Venofix® Safety	Ila
4056501-03	Venofix® Safety	Ila
4056501-04	Venofix® Safety	Ila
4056502-01	Venofix® Safety	Ila
4056502-03	Venofix® Safety	Ila
4056502-04	Venofix® Safety	Ila
4056503-01	Venofix® Safety	Ila
4056503-03	Venofix® Safety	Ila
4056503-04	Venofix® Safety	Ila
4056504-01	Venofix® Safety	Ila
4056504-03	Venofix® Safety	Ila
4056504-04	Venofix® Safety	Ila
4056505-01	Venofix® Safety	Ila
4056505-03	Venofix® Safety	Ila
4056505-04	Venofix® Safety	Ila
4056506-01	Venofix® Safety	Ila
4056506-03	Venofix® Safety	Ila
4056506-04	Venofix® Safety	Ila

Amendment Information

Version	Description of the changes
05	Update due to Expiry Date Add Address of the Notified Body

Title: Declaration of Conformity - 124-100 - Venofix Safety 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, 01 July 2019, 12:11 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Monday, 01 July 2019, 18:50 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Monday, 01 July 2019, 21:50 W. Europe Daylight Time
Meaning: Approve Document
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