

**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**Introcan Safety® 3**

Geschlossener IV-Katheter

(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**
2011-11**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Introcan Safety® 3**

Closed IV Catheter

(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**
2011-11**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4251127-01	Introcan Safety® 3	Ila
4251127-02	Introcan Safety® 3	Ila
4251127-03	Introcan Safety® 3	Ila
4251127-04	Introcan Safety® 3	Ila
4251127IN	Introcan Safety® 3	Ila
4251127JP	Introcan Safety® 3	Ila
4251128-01	Introcan Safety® 3	Ila
4251128-02	Introcan Safety® 3	Ila
4251128-03	Introcan Safety® 3	Ila
4251128-04	Introcan Safety® 3	Ila
4251128IN	Introcan Safety® 3	Ila
4251128JP	Introcan Safety® 3	Ila
4251129-01	Introcan Safety® 3	Ila
4251129-02	Introcan Safety® 3	Ila
4251129-03	Introcan Safety® 3	Ila
4251129-04	Introcan Safety® 3	Ila
4251129JP	Introcan Safety® 3	Ila
4251130-01	Introcan Safety® 3	Ila
4251130-02	Introcan Safety® 3	Ila
4251130-03	Introcan Safety® 3	Ila
4251130-04	Introcan Safety® 3	Ila
4251130IN	Introcan Safety® 3	Ila
4251130JP	Introcan Safety® 3	Ila
4251131-01	Introcan Safety® 3	Ila
4251131-02	Introcan Safety® 3	Ila
4251131-03	Introcan Safety® 3	Ila
4251131-04	Introcan Safety® 3	Ila
4251131JP	Introcan Safety® 3	Ila
4251132-01	Introcan Safety® 3	Ila
4251132-02	Introcan Safety® 3	Ila
4251132-03	Introcan Safety® 3	Ila
4251132-04	Introcan Safety® 3	Ila
4251132IN	Introcan Safety® 3	Ila
4251133-01	Introcan Safety® 3	Ila
4251133-03	Introcan Safety® 3	Ila
4251133-04	Introcan Safety® 3	Ila

4251134-01	Introcan Safety® 3	Ila
4251134-03	Introcan Safety® 3	Ila
4251134-04	Introcan Safety® 3	Ila
4251135-01	Introcan Safety® 3	Ila
4251135-03	Introcan Safety® 3	Ila
4251135-04	Introcan Safety® 3	Ila
4251136-01	Introcan Safety® 3	Ila
4251136-03	Introcan Safety® 3	Ila
4251136-04	Introcan Safety® 3	Ila
4251137-01	Introcan Safety® 3	Ila
4251137-02	Introcan Safety® 3	Ila
4251137-03	Introcan Safety® 3	Ila
4251137-04	Introcan Safety® 3	Ila
4251144-01	Introcan Safety® 3	Ila

Amendment Information

Version	Description of the changes
07	Add article no. 4251136-01, 4251136-03, 4251136-04, 4251133-01, 4251133-03 and 4251133-04
08	Add article no. 4251134-01, 4251134-03, 4251134-04, 4251135-01, 4251135-03, 4251135-04
09	Add article no. 4251144-01
10	Add article no. 4251127JP, 4251128JP, 4251129JP, 4251130JP, 4251131JP
11	Add article no. 4251127IN, 4251128IN, 4251130IN, 4251132IN

Title: Declaration of Conformity - 120-100 - Introcan Safety 3 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: Tuesday, 18 February 2020, 08:49 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Brand, Thomas (brantode)
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Date: Thursday, 20 February 2020, 19:46 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Friday, 21 February 2020, 08:32 W. Europe Daylight Time
Meaning: Approve Document
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