

**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
4251127-03	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
4251128-03	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
4251129-03	Introcan Safety® 3	Ila
4251129-04	Introcan Safety® 3	Ila
4251129JP	Introcan Safety® 3	Ila
4251130-01	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
4251131-03	Introcan Safety® 3	Ila
4251131-04	Introcan Safety® 3	Ila
4251131JP	Introcan Safety® 3	Ila
4251132-01	Introcan Safety® 3	Ila
4251132-03	Introcan Safety® 3	Ila
4251132-04	Introcan Safety® 3	Ila
4251132IN	Introcan Safety® 3	Ila
4251132JP	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
4251137-03	Introcan Safety® 3	Ila
4251137-04	Introcan Safety® 3	Ila
4251144-01	Introcan Safety® 3	Ila

Amendment Information

Version	Description of the changes
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
12	CE mark deleted from labels of US articles and IFU (LLD 3561, 3101, 3021). 1st batch:2017-09-29
13	Add article no. 4251132JP. No change in product or packaging. Change of article code on label only.

Title: Declaration of Conformity - 120-100 - Introcan Safety 3 Initiator: Ulrich ? Jedelhauser

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

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