

**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®,
Introcan Safety®-W**

Venenverweilkanülen

(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**
1994-12**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Introcan Safety®,
Introcan Safety®-W**

I. V. cannulae

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

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4251601-01	Introcan Safety®	Ila
4251601-03	Introcan Safety®	Ila
4251601-04	Introcan Safety®	Ila
4251601JP	Introcan Safety®	Ila
4251607-01	Introcan Safety®	Ila
4251607-03	Introcan Safety®	Ila
4251607-04	Introcan Safety®	Ila
4251607JP	Introcan Safety®	Ila
4251614-01	Introcan Safety®-W	Ila
4251614-03	Introcan Safety®-W	Ila
4251614-04	Introcan Safety®-W	Ila
4251614JP	Introcan Safety®-W	Ila
4251620-01	Introcan Safety®	Ila
4251621-01	Introcan Safety®	Ila
4251622-01	Introcan Safety®	Ila
4251623-01	Introcan Safety®	Ila
4251628	Introcan Safety®	Ila
4251628-01	Introcan Safety®	Ila
4251628-03	Introcan Safety®	Ila
4251628-04	Introcan Safety®	Ila
4251628JP	Introcan Safety®	Ila
4251644	Introcan Safety®	Ila
4251644-01	Introcan Safety®	Ila
4251644-03	Introcan Safety®	Ila
4251644-04	Introcan Safety®	Ila
4251644JP	Introcan Safety®	Ila
4251652-01	Introcan Safety®	Ila
4251652-03	Introcan Safety®	Ila
4251652-04	Introcan Safety®	Ila
4251652JP	Introcan Safety®	Ila
4251679-01	Introcan Safety®	Ila
4251679-03	Introcan Safety®	Ila
4251679-04	Introcan Safety®	Ila
4251679JP	Introcan Safety®	Ila
4251687-01	Introcan Safety®	Ila
4251687-03	Introcan Safety®	Ila
4251687-04	Introcan Safety®	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4251687JP	Introcan Safety®	Ila
4251695-01	Introcan Safety®	Ila
4251695-03	Introcan Safety®	Ila
4251695-04	Introcan Safety®	Ila
4251695JP	Introcan Safety®	Ila
4251709-01	Introcan Safety®	Ila
4251709-03	Introcan Safety®	Ila
4251709-04	Introcan Safety®	Ila
4251709JP	Introcan Safety®	Ila
4251717-01	Introcan Safety®	Ila
4251717-03	Introcan Safety®	Ila
4251717-04	Introcan Safety®	Ila
4251890-01	Introcan Safety®	Ila
4251890-03	Introcan Safety®	Ila
4251890-04	Introcan Safety®	Ila
4252500-01	Introcan Safety®	Ila
4252500-03	Introcan Safety®	Ila
4252500-04	Introcan Safety®	Ila
4252519-01	Introcan Safety®	Ila
4252519-03	Introcan Safety®	Ila
4252519-04	Introcan Safety®	Ila
4252520-01	Introcan Safety®	Ila
4252527-01	Introcan Safety®	Ila
4252527-03	Introcan Safety®	Ila
4252527-04	Introcan Safety®	Ila
4252535-01	Introcan Safety®	Ila
4252535-03	Introcan Safety®	Ila
4252535-04	Introcan Safety®	Ila
4252543-01	Introcan Safety®	Ila
4252543-03	Introcan Safety®	Ila
4252543-04	Introcan Safety®	Ila
4252551-01	Introcan Safety®	Ila
4252551-03	Introcan Safety®	Ila
4252551-04	Introcan Safety®	Ila
4252560-01	Introcan Safety®	Ila
4252560-03	Introcan Safety®	Ila
4252560-04	Introcan Safety®	Ila
4252561-01	Introcan Safety®	Ila
4252578-01	Introcan Safety®	Ila
4252578-03	Introcan Safety®	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4252578-04	Introcan Safety®	Ila
4252586-01	Introcan Safety®	Ila
4252586-03	Introcan Safety®	Ila
4252586-04	Introcan Safety®	Ila
4252594-01	Introcan Safety®	Ila
4252594-03	Introcan Safety®	Ila
4252594-04	Introcan Safety®	Ila
4253523-01	Introcan Safety®-W	Ila
4253523-03	Introcan Safety®-W	Ila
4253523-04	Introcan Safety®-W	Ila
4253523JP	Introcan Safety®-W	Ila
4253540-01	Introcan Safety®-W	Ila
4253540-03	Introcan Safety®-W	Ila
4253540-04	Introcan Safety®-W	Ila
4253540JP	Introcan Safety®-W	Ila
4253566-01	Introcan Safety®-W	Ila
4253566-03	Introcan Safety®-W	Ila
4253566-04	Introcan Safety®-W	Ila
4253566JP	Introcan Safety®-W	Ila
4253574-01	Introcan Safety®-W	Ila
4253574-03	Introcan Safety®-W	Ila
4253574-04	Introcan Safety®-W	Ila
4253574JP	Introcan Safety®-W	Ila
4253590-01	Introcan Safety®-W	Ila
4253590-03	Introcan Safety®-W	Ila
4253590-04	Introcan Safety®-W	Ila
4253604-01	Introcan Safety®-W	Ila
4253604-03	Introcan Safety®-W	Ila
4253604-04	Introcan Safety®-W	Ila
4253604JP	Introcan Safety®-W	Ila
4253612-01	Introcan Safety®-W	Ila
4253612-03	Introcan Safety®-W	Ila
4253612-04	Introcan Safety®-W	Ila
4253639-01	Introcan Safety®-W	Ila
4253639-03	Introcan Safety®-W	Ila
4253639-04	Introcan Safety®-W	Ila
4254503-01	Introcan Safety®-W	Ila
4254503-03	Introcan Safety®-W	Ila
4254503-04	Introcan Safety®-W	Ila
4254511	Introcan Safety®-W	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4254511-01	Introcan Safety®-W	Ila
4254511-03	Introcan Safety®-W	Ila
4254511-04	Introcan Safety®-W	Ila
4254538	Introcan Safety®-W	Ila
4254538-01	Introcan Safety®-W	Ila
4254538-03	Introcan Safety®-W	Ila
4254538-04	Introcan Safety®-W	Ila
4254546	Introcan Safety®-W	Ila
4254546-01	Introcan Safety®-W	Ila
4254546-03	Introcan Safety®-W	Ila
4254546-04	Introcan Safety®-W	Ila
4254554-01	Introcan Safety®-W	Ila
4254554-03	Introcan Safety®-W	Ila
4254554-04	Introcan Safety®-W	Ila
4254562-01	Introcan Safety®-W	Ila
4254562-03	Introcan Safety®-W	Ila
4254562-04	Introcan Safety®-W	Ila
4254570	Introcan Safety®-W	Ila
4254570-01	Introcan Safety®-W	Ila
4254570-03	Introcan Safety®-W	Ila
4254570-04	Introcan Safety®-W	Ila
4254597-01	Introcan Safety®-W	Ila
4254597-03	Introcan Safety®-W	Ila
4254597-04	Introcan Safety®-W	Ila

Amendment Information

Version	Description of the changes
06	Add art. no. 4251620-01, 4251621-01, 4251622-01, 4251623-01 Delete Out of Market Article: 4251601, 4251611, 4251652, 4251687, 4251695, 4251709, 4251717, 4251890, 4252500, 4252511, 4252520, 4252527, 4252535, 4252543, 4252560, 4252561, 4252586, 4252594, 4253511, 4253523, 4253540, 4253566, 4253574, 4253590, 4253604, 4253612, 4253639, 4254512, 4254554, 4254562, 4254597, 4251679, 4252551, 4254503, 4252519, 4252578
07	Add art. no. 4251601JP, 4251607JP, 4251628JP, 4251644JP, 4251652JP, 4251679JP, 4251687JP, 4251695JP, 4251709JP, 4251614JP, 4253523JP, 4253540JP, 4253566JP, 4253574JP, 4253604JP
08	CE mark deleted from labels and IFU for US articles (LLD 3427, 2615, 3216, 2428). 1st batch: 2017-06-22

Title: Declaration of Conformity - 120-010 - Introcan Safety Initiator: Marie Fischer

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

UserName: Fischer, Marie (fiscm3de)
Title: Administrator RA International CoE Infusion & Pain Therapy
Date: Tuesday, 27 September 2022, 08:07 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Tuesday, 27 September 2022, 16:24 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: Wednesday, 28 September 2022, 18:34 W. Europe Daylight Time
Meaning: Approve Document
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