

**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  
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**  
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 14<sup>th</sup>  
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**  
1994-12**Valid until**  
2024-05-26

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4251601-01	Introcan Safety®	Ila
4251601-02	Introcan Safety®	Ila
4251601-03	Introcan Safety®	Ila
4251601-04	Introcan Safety®	Ila
4251601JP	Introcan Safety®	Ila
4251607-01	Introcan Safety®	Ila
4251607-02	Introcan Safety®	Ila
4251607-03	Introcan Safety®	Ila
4251607-04	Introcan Safety®	Ila
4251607JP	Introcan Safety®	Ila
4251609-02	Introcan Safety®-W	Ila
4251611-02	Introcan Safety®	Ila
4251612-02	Introcan Safety®	Ila
4251614-01	Introcan Safety®-W	Ila
4251614-02	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
4251628-02	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
4251644-02	Introcan Safety®	Ila
4251644-03	Introcan Safety®	Ila
4251644-04	Introcan Safety®	Ila
4251644JP	Introcan Safety®	Ila
4251652-01	Introcan Safety®	Ila
4251652-02	Introcan Safety®	Ila
4251652-03	Introcan Safety®	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4251652-04	Introcan Safety®	Ila
4251652JP	Introcan Safety®	Ila
4251679-01	Introcan Safety®	Ila
4251679-02	Introcan Safety®	Ila
4251679-03	Introcan Safety®	Ila
4251679-04	Introcan Safety®	Ila
4251679JP	Introcan Safety®	Ila
4251687-01	Introcan Safety®	Ila
4251687-02	Introcan Safety®	Ila
4251687-03	Introcan Safety®	Ila
4251687-04	Introcan Safety®	Ila
4251687JP	Introcan Safety®	Ila
4251695-01	Introcan Safety®	Ila
4251695-02	Introcan Safety®	Ila
4251695-03	Introcan Safety®	Ila
4251695-04	Introcan Safety®	Ila
4251695JP	Introcan Safety®	Ila
4251709-01	Introcan Safety®	Ila
4251709-02	Introcan Safety®	Ila
4251709-03	Introcan Safety®	Ila
4251709-04	Introcan Safety®	Ila
4251709JP	Introcan Safety®	Ila
4251717-01	Introcan Safety®	Ila
4251717-02	Introcan Safety®	Ila
4251717-03	Introcan Safety®	Ila
4251717-04	Introcan Safety®	Ila
4251890-01	Introcan Safety®	Ila
4251890-02	Introcan Safety®	Ila
4251890-03	Introcan Safety®	Ila
4251890-04	Introcan Safety®	Ila
4252500-01	Introcan Safety®	Ila
4252500-02	Introcan Safety®	Ila
4252500-03	Introcan Safety®	Ila
4252500-04	Introcan Safety®	Ila
4252511-02	Introcan Safety®	Ila
4252519-01	Introcan Safety®	Ila
4252519-02	Introcan Safety®	Ila
4252519-03	Introcan Safety®	Ila
4252519-04	Introcan Safety®	Ila
4252520-01	Introcan Safety®	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4252520-02	Introcan Safety®	Ila
4252527-01	Introcan Safety®	Ila
4252527-02	Introcan Safety®	Ila
4252527-03	Introcan Safety®	Ila
4252527-04	Introcan Safety®	Ila
4252535-01	Introcan Safety®	Ila
4252535-02	Introcan Safety®	Ila
4252535-03	Introcan Safety®	Ila
4252535-04	Introcan Safety®	Ila
4252543-01	Introcan Safety®	Ila
4252543-02	Introcan Safety®	Ila
4252543-03	Introcan Safety®	Ila
4252543-04	Introcan Safety®	Ila
4252551-01	Introcan Safety®	Ila
4252551-02	Introcan Safety®	Ila
4252551-03	Introcan Safety®	Ila
4252551-04	Introcan Safety®	Ila
4252560-01	Introcan Safety®	Ila
4252560-02	Introcan Safety®	Ila
4252560-03	Introcan Safety®	Ila
4252560-04	Introcan Safety®	Ila
4252561-01	Introcan Safety®	Ila
4252561-02	Introcan Safety®	Ila
4252578-01	Introcan Safety®	Ila
4252578-02	Introcan Safety®	Ila
4252578-03	Introcan Safety®	Ila
4252578-04	Introcan Safety®	Ila
4252586-01	Introcan Safety®	Ila
4252586-02	Introcan Safety®	Ila
4252586-03	Introcan Safety®	Ila
4252586-04	Introcan Safety®	Ila
4252594-01	Introcan Safety®	Ila
4252594-02	Introcan Safety®	Ila
4252594-03	Introcan Safety®	Ila
4252594-04	Introcan Safety®	Ila
4253511-02	Introcan Safety®-W	Ila
4253523-01	Introcan Safety®-W	Ila
4253523-02	Introcan Safety®-W	Ila
4253523-03	Introcan Safety®-W	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4253523-04	Introcan Safety®-W	Ila
4253523JP	Introcan Safety®-W	Ila
4253540-01	Introcan Safety®-W	Ila
4253540-02	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
4253566-02	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
4253574-02	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
4253590-02	Introcan Safety®-W	Ila
4253590-03	Introcan Safety®-W	Ila
4253590-04	Introcan Safety®-W	Ila
4253604-01	Introcan Safety®-W	Ila
4253604-02	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
4253612-02	Introcan Safety®-W	Ila
4253612-03	Introcan Safety®-W	Ila
4253612-04	Introcan Safety®-W	Ila
4253639-01	Introcan Safety®-W	Ila
4253639-02	Introcan Safety®-W	Ila
4253639-03	Introcan Safety®-W	Ila
4253639-04	Introcan Safety®-W	Ila
4254503-01	Introcan Safety®-W	Ila
4254503-02	Introcan Safety®-W	Ila
4254503-03	Introcan Safety®-W	Ila
4254503-04	Introcan Safety®-W	Ila
4254511	Introcan Safety®-W	Ila
4254511-01	Introcan Safety®-W	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4254511-02	Introcan Safety®-W	Ila
4254511-03	Introcan Safety®-W	Ila
4254511-04	Introcan Safety®-W	Ila
4254512-02	Introcan Safety®-W	Ila
4254538	Introcan Safety®-W	Ila
4254538-01	Introcan Safety®-W	Ila
4254538-02	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
4254546-02	Introcan Safety®-W	Ila
4254546-03	Introcan Safety®-W	Ila
4254546-04	Introcan Safety®-W	Ila
4254554-01	Introcan Safety®-W	Ila
4254554-02	Introcan Safety®-W	Ila
4254554-03	Introcan Safety®-W	Ila
4254554-04	Introcan Safety®-W	Ila
4254562-01	Introcan Safety®-W	Ila
4254562-02	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
4254570-02	Introcan Safety®-W	Ila
4254570-03	Introcan Safety®-W	Ila
4254570-04	Introcan Safety®-W	Ila
4254597-01	Introcan Safety®-W	Ila
4254597-02	Introcan Safety®-W	Ila
4254597-03	Introcan Safety®-W	Ila
4254597-04	Introcan Safety®-W	Ila

**Amendment Information**

<b>Version</b>	<b>Description of the changes</b>
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

Title: Declaration of Conformity - 120-010 - Introcan 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)  
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Date: Tuesday, 12 November 2019, 07:28 W. Europe Daylight Time  
Meaning: Document signed as Author  
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UserName: Brand, Thomas (brantode)  
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Date: Wednesday, 13 November 2019, 08:20 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: Thursday, 14 November 2019, 15:44 W. Europe Daylight Time  
Meaning: Approve Document  
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