

**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 14<sup>th</sup> 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**

| <b>Art.-Nr. / Art. No.</b> | <b>Produktname / Product name</b> | <b>Klasse / Class</b> |
|----------------------------|-----------------------------------|-----------------------|
| 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                   |
| 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                                                                         |
|---------|----------------------------------------------------------------------------------------------------|
| 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                                         |
| 12      | CE mark deleted from labels of US articles and IFU (LLD 3561, 3101, 3021).<br>1st batch:2017-09-29 |

Title: Declaration of Conformity - 120-100 - Introcan Safety 3 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, 04 October 2022, 08:08 W. Europe Daylight Time  
Meaning: Document signed as Author  
=====

UserName: Seidel, Stefan (seidstde)  
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy  
Date: Wednesday, 05 October 2022, 17:34 W. Europe Daylight Time  
Meaning: Approve Document  
=====

UserName: Brand, Thomas (brantode)  
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices  
Date: Tuesday, 11 October 2022, 21:15 W. Europe Daylight Time  
Meaning: Approve Document  
=====

Noi,

**B. Braun Melsungen AG**  
**Carl-Braun Straße 1**  
**34212 Melsungen**  
**Germania**

dichiariamo sotto la nostra responsabilità che i prodotti

**Introcan Safety® 3**

Catetere IV chiuso  
(vedere codici articoli nell'allegato I)

sono conformi alla seguente direttiva

Direttiva Europea 93/42/CEE del 14 giugno  
1993  
sui dispositivi medici  
modificata dalla Direttiva 2007/47/CE

**Procedura di valutazione della conformità**  
secondo l'allegato II (esclusa la sezione 4)  
della Direttiva sopra menzionata

**Classificazione**  
secondo l'allegato IX  
della Direttiva Europea sopra menzionata  
Classe IIa

**Ente Notificatore**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 Monaco  
Germania  
Numero identificativo 0123

**Data del primo marchio CE**

11-2011

**Valido fino al**  
26-05-2024

traduzione

Dichiarazione di conformità

Documento N.: 120-100  
Versione: 12.0  
Data effettiva: 11-10-2022

Dichiarazione di conformità

**Allegato I**

Codice

nome prodotto

classe di rischio

**Si prega di fare riferimento ai codici elencati nella dichiarazione originale**

| Versione | Descrizione del cambiamento                                                                                     |
|----------|-----------------------------------------------------------------------------------------------------------------|
| 07       | Aggiunta articoli n. 4251136-01, 4251136-03, 4251136-04, 4251133-01, 4251133-03 e 4251133-04                    |
| 08       | Aggiunta articoli n. 4251134-01, 4251134-03, 4251134-04, 4251135-01, 4251135-03, 4251135-04                     |
| 09       | Aggiunta articoli n. 4251144-01                                                                                 |
| 10       | Aggiunta articoli n. 4251127JP, 4251128JP, 4251129JP, 4251130JP, 4251131JP                                      |
| 11       | Aggiunta articoli n. 4251127IN, 4251128IN, 4251130IN, 4251132IN                                                 |
| 12       | Marchio CE eliminato da etichette e IFU degli articoli statunitensi (LLD 3561, 3101, 3021). 1° lotto:29-09-2017 |