

**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® 2**

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**
2020-03**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Introcan Safety® 2**

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**
2020-03**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4232000-01	Introcan Safety® 2	Ila
4232001-01	Introcan Safety® 2	Ila
4232002-01	Introcan Safety® 2	Ila
4232003-01	Introcan Safety® 2	Ila
4232004-01	Introcan Safety® 2	Ila
4232005-01	Introcan Safety® 2	Ila
4232006-01	Introcan Safety® 2	Ila
4232007-01	Introcan Safety® 2	Ila
4232008-01	Introcan Safety® 2	Ila
4232009-01	Introcan Safety® 2	Ila
4232010-01	Introcan Safety® 2	Ila
4232011-01	Introcan Safety® 2	Ila
4232012-01	Introcan Safety® 2	Ila
4232013-01	Introcan Safety® 2	Ila
4232014-01	Introcan Safety® 2	Ila
4232015-01	Introcan Safety® 2	Ila

Amendment Information

Version	Description of the changes
01	First version for art. no. 4232000-01, 4232002-01, 4232004-01, 4232006-01, 4232008-01, 4232010-01, 4232012-01, 4232014-01
02	Add art. no. 4232001-01, 4232003-01, 4232005-01, 4232007-01, 4232009-01, 4232011-01, 4232013-01, 4232015-01

Title: Declaration of Conformity - 120-120 - Introcan Safety 2 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: Thursday, 23 April 2020, 06:59 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Thursday, 23 April 2020, 07:32 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: Tuesday, 28 April 2020, 17:56 W. Europe Daylight Time
Meaning: Approve Document
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