

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201**erklären in eigener Verantwortung,
dass das/die Produkt/e**Introcan Safety® 2**
Closed IV Catheter

(Artikelnummern und Basic UDI-DI siehe Anlage I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/übereinstimmen**Konformitätsbewertungsverfahren**
nach Anhang IX**Klassifizierung**
gemäß Anhang VIII der oben genannten
Verordnung
Klasse IIa**Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**
gemäß gültigem (Nr. G10 012974 0611)hereby declare in our own responsibility
that the product/s**Introcan Safety® 2**
Closed IV Catheter

(article numbers and Basic UDI-DI see attachment I)

is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745**Conformity Assessment Procedure**
according to annex IX**Classification**
according to annex VIII of the Regulation named
above
Class IIa**Notified Body**
TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**
gemäß gültigem (Nr. G10 012974 0611)

Anlage I / Attachment I**Basic UDI-DI 40392390000007662Y**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4242000-01	Introcan Safety [®] 2	Ila
4242001-01	Introcan Safety [®] 2-W	Ila
4242002-01	Introcan Safety [®] 2	Ila
4242003-01	Introcan Safety [®] 2-W	Ila
4242004-01	Introcan Safety [®] 2	Ila
4242005-01	Introcan Safety [®] 2-W	Ila
4242006-01	Introcan Safety [®] 2	Ila
4242007-01	Introcan Safety [®] 2-W	Ila
4242008-01	Introcan Safety [®] 2	Ila
4242009-01	Introcan Safety [®] 2-W	Ila
4242010-01	Introcan Safety [®] 2	Ila
4242011-01	Introcan Safety [®] 2-W	Ila
4242012-01	Introcan Safety [®] 2	Ila
4242013-01	Introcan Safety [®] 2-W	Ila
4242014-01	Introcan Safety [®] 2	Ila
4242015-01	Introcan Safety [®] 2-W	Ila
---	Portfolio Deep Access	---
4242024-01	Introcan Safety [®] 2	Ila
4242025-01	Introcan Safety [®] 2	Ila
4242026-01	Introcan Safety [®] 2	Ila
4242027-01	Introcan Safety [®] 2	Ila
4242028-01	Introcan Safety [®] 2	Ila

Basic UDI-DI 40392390000007662Y

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
Portfolio AP / -03 article codes		
4242000-03	Introcan Safety [®] 2	Ila
4242001-03	Introcan Safety [®] 2-W	Ila
4242002-03	Introcan Safety [®] 2	Ila
4242003-03	Introcan Safety [®] 2-W	Ila
4242004-03	Introcan Safety [®] 2	Ila
4242005-03	Introcan Safety [®] 2-W	Ila
4242006-03	Introcan Safety [®] 2	Ila
4242007-03	Introcan Safety [®] 2-W	Ila
4242008-03	Introcan Safety [®] 2	Ila
4242009-03	Introcan Safety [®] 2-W	Ila
4242010-03	Introcan Safety [®] 2	Ila
4242011-03	Introcan Safety [®] 2-W	Ila
4242012-03	Introcan Safety [®] 2	Ila
4242013-03	Introcan Safety [®] 2-W	Ila
4242014-03	Introcan Safety [®] 2	Ila
4242015-03	Introcan Safety [®] 2-W	Ila
Portfolio CN / China article codes		
4242000CN	Introcan Safety [®] 2	Ila
4242001CN	Introcan Safety [®] 2-W	Ila
4242002CN	Introcan Safety [®] 2	Ila
4242003CN	Introcan Safety [®] 2-W	Ila
4242004CN	Introcan Safety [®] 2	Ila
4242005CN	Introcan Safety [®] 2-W	Ila
4242006CN	Introcan Safety [®] 2	Ila
4242007CN	Introcan Safety [®] 2-W	Ila
4242008CN	Introcan Safety [®] 2	Ila
4242009CN	Introcan Safety [®] 2-W	Ila
4242010CN	Introcan Safety [®] 2	Ila
4242011CN	Introcan Safety [®] 2-W	Ila
4242012CN	Introcan Safety [®] 2	Ila
4242013CN	Introcan Safety [®] 2-W	Ila
4242014CN	Introcan Safety [®] 2	Ila
4242015CN	Introcan Safety [®] 2-W	Ila

Document amendment information

Version	Description of the changes
1.0	Creation of the document
2.0	Addition of article numbers 4242001-01, 4242003-01, 4242005-01, 4242007-01, 4242009-01, 4242011-01, 4242013-01, 4242015-01
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4.0	Addition of article numbers 4242024-01, 4242025-01, 4242026-01, 4242028-01; Project F.407-2112.02-8-D1-04-04 (Introcan Safety 2 Deep Access)
5.0	Addition of article numbers Portfolio AP / -03: 4242000-03, 4242001-03, 4242002-03, 4242003-03, 4242004-03, 4242005-03, 4242006-03, 4242007-03, 4242008-03, 4242009-03, 4242010-03, 4242011-03, 4242012-03, 4242013-03, 4242014-03, 4242015-03 Addition of article numbers Portfolio CN / China: 4242000CN, 4242001CN, 4242002CN, 4242003CN, 4242004CN, 4242005CN, 4242006CN, 4242007CN, 4242008CN, 4242009CN, 4242010CN, 4242011CN, 4242012CN, 4242013CN, 4242014CN, 4242015CN

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