

**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**Mandrin/Stylet Introcan®,  
Mandrin/Stylet Vasofix®/Vasocan®**  
Mandrins

(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**Mandrin/Stylet Introcan®,  
Mandrin/Stylet Vasofix®/Vasocan®**  
Stylets

(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>
4214099	Mandrin/Stylet Introcan®	Ila
4214110	Mandrin/Stylet Introcan®	Ila
4214137	Mandrin/Stylet Introcan®	Ila
4214170	Mandrin/Stylet Introcan®	Ila
4214218	Mandrin/Stylet Introcan®	Ila
4214323	Mandrin/Stylet Introcan®	Ila
4215095	Mandrin/Stylet Vasofix®/Vasocan®	Ila
4215117	Mandrin/Stylet Vasofix®/Vasocan®	Ila
4215150	Mandrin/Stylet Vasofix®/Vasocan®	Ila
4219104	Mandrin/Stylet Vasofix®/Vasocan®	Ila
4219120	Mandrin/Stylet Vasofix®/Vasocan®	Ila
4219139	Mandrin/Stylet Vasofix®/Vasocan®	Ila
4219171	Mandrin/Stylet Vasofix®/Vasocan®	Ila
4219201	Mandrin/Stylet Vasofix®/Vasocan®	Ila

**Amendment Information**

<b>Version</b>	<b>Description of the changes</b>
05	Update TÜV address
06	Update validity

Title: Declaration of Conformity - 122-001 - Mandrin Stylet 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, 05 March 2020, 11:00 W. Europe Daylight Time  
Meaning: Document signed as Author  
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UserName: Brand, Thomas (brantode)  
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices  
Date: Saturday, 07 March 2020, 21:48 W. Europe Daylight Time  
Meaning: Approve Document  
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UserName: Seidel, Stefan (seidstde)  
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Date: Thursday, 12 March 2020, 12:34 W. Europe Daylight Time  
Meaning: Approve Document  
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