

Wir

We

**B. Braun Melsungen AG  
Carl-Braun-Straße 1  
34212 Melsungen  
Deutschland/Germany**erklären in eigener Verantwortung,  
dass das/die Produkt/e**Intradyn Tear-Away**Einführbestecke  
(Artikelnummern siehe Anlage )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 / Regel 7**Benannte Stelle**  
TÜV SÜD Product Service GmbH (ID-Nr. 0123)  
Ridlerstraße 65, 80339 München, Deutschland**Ausgestellte Bescheinigung(en):**  
G1 012974 0608 Rev. 00**Datum der ersten CE-Kennzeichnung**  
1998-11-13**Gültig bis**  
2024-05-26hereby declare in our own responsibility  
that the product/s**Intradyn Tear-Away**Introducers  
(article numbers see attachment )

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 / Rule 7**Notified Body**  
TÜV SÜD Product Service GmbH (ID no. 0123)  
Ridlerstraße 65, 80339 Munich, Germany**Certificate(s) issued:**  
G1 012974 0608 Rev. 00**Date of first CE-marking**  
1998-11-13**Valid until**  
2024-05-26

Berlin, 2021-02-03

B. Braun Melsungen AG

i. A.

  
Dr. S. Vogelbein  
Head of Quality Management CoE VS

Berlin, 2021-02-03

B. Braun Melsungen AG

i. V.

  
Dr. H. Schlicht  
Head of Regulatory Affairs

Effective

**Anlage I / Attachment I**

<b>Art.-Nr. REF No.</b>	<b>Artikelbezeichnung</b>	<b>Article description</b>	<b>Klasse Class</b>
5010848	Tear Away Introducer 7cm 4 F	Peelable Introducer 7cm 4 F	IIa
5010849	Tear Away Introducer 7cm 5 F	Peelable Introducer 7cm 5 F	IIa
5010851	Tear Away Introducer 7cm 6 F	Peelable Introducer 7cm 6 F	IIa
5210313	Intradyn Tear-Away F6	Intradyn Tear-Away F6 with J3 Wire	IIa
5210593	Intradyn Tear-Away F7	Intradyn Tear-Away F7	IIa
5210321	Intradyn Tear-Away F8	Intradyn Tear-Away F8	IIa
5210330	Intradyn Tear-Away F9	Intradyn Tear-Away F9	IIa
5210348	Intradyn Tear-Away F10	Intradyn Tear-Away F10 with J3 Wire	IIa
5214297	Intradyn Tear-Away F10,5	Intradyn Tear-Away F10.5	IIa
5210585	Intradyn Tear-Away F11	Intradyn Tear-Away F11	IIa
5014882	Tear Away Introducer 7cm 4.5 F	Tear Away Introducer 7cm 4.5 F	IIa
5014883	Tear Away Introducer 7cm 5.5 F	Tear Away Introducer 7cm 5.5 F	IIa
5014884	Tear Away Introducer 7cm 6.5 F	Tear Away Introducer 7cm 6.5 F	IIa
5211869	Intradyn Tear-Away F6 16 cm	Intradyn Tear-Away F6 16 cm	IIa
5211870	Intradyn Tear-Away F4 14 cm	Intradyn Tear-Away F4 14 cm	IIa
5212537	Intradyn dual Tear-Away F10	Intradyn dual Tear-Away F10	IIa
5214698	Splittbares Einführbesteck mit Ventil 9F	Valved peelable Introducer 9F	IIa
5214699	Splittbares Einführbesteck mit Ventil 7F	Valved peelable Introducer 7F	IIa

Title: Intradyn-TA\_39.05.629\_DOC Initiator: Annesha ? Lahiri

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Lahiri, Annesha (lahiande)  
Title: Regulatory Affairs Manager  
Date: Wednesday, 12 May 2021, 17:51 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Schlicht, Henning (schlhgde)  
Title: Head of Regulatory Affairs  
Date: Friday, 14 May 2021, 14:54 W. Europe Daylight Time  
Meaning: Approve Document

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