

Wir

We

**B. Braun Melsungen AG  
Carl-Braun-Straße 1  
34212 Melsungen  
Deutschland/Germany**erklären in eigener Verantwortung,  
dass das/die Produkt/e**Coroflex ISAR**  
Koronares Stent System  
(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, II.4  
der oben genannten Richtlinie**Klassifizierung**  
gemäß Anhang IX der  
oben genannten Richtlinie  
Klasse III / Regeln 6 und 13**Benannte Stelle**  
DEKRA Certification GmbH (ID-Nr. 0124)  
Handwerkstraße 15, 70565 Stuttgart, Deutschland**Ausgestellte Bescheinigung(en):**  
51342-16-02  
51342-23-C1**Datum der ersten CE-Kennzeichnung**  
2014-02-04**Gültig bis**  
2021-08-25hereby declare in our own responsibility  
that the product/s**Coroflex ISAR**  
Coronary Stent System  
(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, II.4  
of the Council Directive named above**Classification**  
according to annex IX of the  
Council Directive named above  
Class III / Rules 6 and 13**Notified Body**  
DEKRA Certification GmbH (ID-No. 0124)  
Handwerkstraße 15, 70565 Stuttgart, Germany**Certificate(s) issued:**  
51342-16-02  
51342-23-C1**Date of first CE-marking**  
2014-02-04**Valid until**  
2021-08-25

Berlin, 2020-09-01

Berlin, 2020-09-01

B. Braun Melsungen AG

B. Braun Melsungen AG

i. A.

Dr. S. Vogelbein  
Head of Quality Management CoE VS

i. V.

Dr. H. Schlicht  
Head of Regulatory Affairs

**Anlage I / Annex I**

<b>Art.-Nr. / Art. No.</b>	<b>Artikelbezeichnung</b>	<b>Article description</b>	<b>Klasse / Class</b>
5028700	Coroflex ISAR 2.0 x 9 mm	Coroflex ISAR 2.0 x 9 mm	III
5028701	Coroflex ISAR 2.25 x 9 mm	Coroflex ISAR 2.25 x 9 mm	III
5028702	Coroflex ISAR 2.5 x 9 mm	Coroflex ISAR 2.5 x 9 mm	III
5028703	Coroflex ISAR 2.75 x 8 mm	Coroflex ISAR 2.75 x 8 mm	III
5028704	Coroflex ISAR 3.0 x 8 mm	Coroflex ISAR 3.0 x 8 mm	III
5028705	Coroflex ISAR 3.5 x 8 mm	Coroflex ISAR 3.5 x 8 mm	III
5028706	Coroflex ISAR 4.0 x 8 mm	Coroflex ISAR 4.0 x 8 mm	III
5028710	Coroflex ISAR 2.0 x 14 mm	Coroflex ISAR 2.0 x 14 mm	III
5028711	Coroflex ISAR 2.25 x 14 mm	Coroflex ISAR 2.25 x 14 mm	III
5028712	Coroflex ISAR 2.5 x 14 mm	Coroflex ISAR 2.5 x 14 mm	III
5028713	Coroflex ISAR 2.75 x 13 mm	Coroflex ISAR 2.75 x 13 mm	III
5028714	Coroflex ISAR 3.0 x 13 mm	Coroflex ISAR 3.0 x 13 mm	III
5028715	Coroflex ISAR 3.5 x 13 mm	Coroflex ISAR 3.5 x 13 mm	III
5028716	Coroflex ISAR 4.0 x 13 mm	Coroflex ISAR 4.0 x 13 mm	III
5028720	Coroflex ISAR 2.0 x 16 mm	Coroflex ISAR 2.0 x 16 mm	III
5028721	Coroflex ISAR 2.25 x 16 mm	Coroflex ISAR 2.25 x 16 mm	III
5028722	Coroflex ISAR 2.5 x 16 mm	Coroflex ISAR 2.5 x 16 mm	III
5028723	Coroflex ISAR 2.75 x 16 mm	Coroflex ISAR 2.75 x 16 mm	III
5028724	Coroflex ISAR 3.0 x 16 mm	Coroflex ISAR 3.0 x 16 mm	III
5028725	Coroflex ISAR 3.5 x 16 mm	Coroflex ISAR 3.5 x 16 mm	III
5028726	Coroflex ISAR 4.0 x 16 mm	Coroflex ISAR 4.0 x 16 mm	III
5028730	Coroflex ISAR 2.0 x 19 mm	Coroflex ISAR 2.0 x 19 mm	III
5028731	Coroflex ISAR 2.25 x 19 mm	Coroflex ISAR 2.25 x 19 mm	III
5028732	Coroflex ISAR 2.5 x 19 mm	Coroflex ISAR 2.5 x 19 mm	III
5028733	Coroflex ISAR 2.75 x 19 mm	Coroflex ISAR 2.75 x 19 mm	III
5028734	Coroflex ISAR 3.0 x 19 mm	Coroflex ISAR 3.0 x 19 mm	III
5028735	Coroflex ISAR 3.5 x 19 mm	Coroflex ISAR 3.5 x 19 mm	III
5028736	Coroflex ISAR 4.0 x 19 mm	Coroflex ISAR 4.0 x 19 mm	III
5028740	Coroflex ISAR 2.0 x 24 mm	Coroflex ISAR 2.0 x 24 mm	III
5028741	Coroflex ISAR 2.25 x 24 mm	Coroflex ISAR 2.25 x 24 mm	III
5028742	Coroflex ISAR 2.5 x 24 mm	Coroflex ISAR 2.5 x 24 mm	III
5028743	Coroflex ISAR 2.75 x 24 mm	Coroflex ISAR 2.75 x 24 mm	III
5028744	Coroflex ISAR 3.0 x 24 mm	Coroflex ISAR 3.0 x 24 mm	III
5028745	Coroflex ISAR 3.5 x 24 mm	Coroflex ISAR 3.5 x 24 mm	III
5028746	Coroflex ISAR 4.0 x 24 mm	Coroflex ISAR 4.0 x 24 mm	III
5028764	Coroflex ISAR 2.0 x 27 mm	Coroflex ISAR 2.0 x 27 mm	III
5028750	Coroflex ISAR 2.25 x 27 mm	Coroflex ISAR 2.25 x 27 mm	III
5028751	Coroflex ISAR 2.5 x 27 mm	Coroflex ISAR 2.5 x 27 mm	III
5028767	Coroflex ISAR 2.75 x 27 mm	Coroflex ISAR 2.75 x 27 mm	III

<b>Art.-Nr. / Art. No.</b>	<b>Artikelbezeichnung</b>	<b>Article description</b>	<b>Klasse / Class</b>
5028752	Coroflex ISAR 3.0 x 27 mm	Coroflex ISAR 3.0 x 27 mm	III
5028753	Coroflex ISAR 3.5 x 27 mm	Coroflex ISAR 3.5 x 27 mm	III
5028754	Coroflex ISAR 4.0 x 27 mm	Coroflex ISAR 4.0 x 27 mm	III
5028765	Coroflex ISAR 2.0 x 32 mm	Coroflex ISAR 2.0 x 32 mm	III
5028766	Coroflex ISAR 2.25 x 32 mm	Coroflex ISAR 2.25 x 32 mm	III
5028760	Coroflex ISAR 2.5 x 32 mm	Coroflex ISAR 2.5 x 32 mm	III
5028768	Coroflex ISAR 2.75 x 32 mm	Coroflex ISAR 2.75 x 32 mm	III
5028761	Coroflex ISAR 3.0 x 32 mm	Coroflex ISAR 3.0 x 32 mm	III
5028762	Coroflex ISAR 3.5 x 32 mm	Coroflex ISAR 3.5 x 32 mm	III
5028763	Coroflex ISAR 4.0 x 32 mm	Coroflex ISAR 4.0 x 32 mm	III

Effective

Title: Coroflex ISAR\_39.05.657\_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)  
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Meaning: Approve Document

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