

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 NEO**  
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-G1**Datum der ersten CE-Kennzeichnung**

2016-03-15

**Gültig bis**

2024-05-26

hereby declare in our own responsibility  
that the product/s**Coroflex ISAR NEO**  
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-G1**Date of first CE-marking**

2016-03-15

**Valid until**

2024-05-26

Berlin, 2021-05-04

B. Braun Melsungen AG

i. V.

  
Dr. S. Vogelbein  
Head of Quality Management

Berlin, 2021-05-04

B. Braun Melsungen AG

i. V.

  
Dr. H. Schlicht  
Head of Regulatory Affairs**Effective**

**Anlage I / Annex I**

<b>Art.-Nr. / REF No.<sup>1</sup></b>	<b>Art.-Nr. / REF No.<sup>2</sup></b>	<b>Article description</b>	<b>Klasse / Class</b>
5028910	5028910D	Coroflex ISAR NEO 2.00 x 9 mm	III
5028911	5028911D	Coroflex ISAR NEO 2.25 x 9 mm	III
5028912	5028912D	Coroflex ISAR NEO 2.50 x 9 mm	III
5028913	5028913D	Coroflex ISAR NEO 2.75 x 9 mm	III
5028914	5028914D	Coroflex ISAR NEO 3.00 x 9 mm	III
5028915	5028915D	Coroflex ISAR NEO 3.50 x 9 mm	III
5028916	5028916D	Coroflex ISAR NEO 4.00 x 9 mm	III
5028917	5028917D	Coroflex ISAR NEO 2.00 x 12 mm	III
5028918	5028918D	Coroflex ISAR NEO 2.25 x 12 mm	III
5028919	5028919D	Coroflex ISAR NEO 2.50 x 12 mm	III
5028920	5028920D	Coroflex ISAR NEO 2.75 x 12 mm	III
5028921	5028921D	Coroflex ISAR NEO 3.00 x 12 mm	III
5028922	5028922D	Coroflex ISAR NEO 3.50 x 12 mm	III
5028923	5028923D	Coroflex ISAR NEO 4.00 x 12 mm	III
5028924	5028924D	Coroflex ISAR NEO 2.00 x 16 mm	III
5028925	5028925D	Coroflex ISAR NEO 2.25 x 16 mm	III
5028926	5028926D	Coroflex ISAR NEO 2.50 x 16 mm	III
5028927	5028927D	Coroflex ISAR NEO 2.75 x 16 mm	III
5028928	5028928D	Coroflex ISAR NEO 3.00 x 16 mm	III
5028929	5028929D	Coroflex ISAR NEO 3.50 x 16 mm	III
5028930	5028930D	Coroflex ISAR NEO 4.00 x 16 mm	III
5028931	5028931D	Coroflex ISAR NEO 2.00 x 19 mm	III
5028932	5028932D	Coroflex ISAR NEO 2.25 x 19 mm	III
5028933	5028933D	Coroflex ISAR NEO 2.50 x 19 mm	III
5028934	5028934D	Coroflex ISAR NEO 2.75 x 19 mm	III
5028935	5028935D	Coroflex ISAR NEO 3.00 x 19 mm	III
5028936	5028936D	Coroflex ISAR NEO 3.50 x 19 mm	III
5028937	5028937D	Coroflex ISAR NEO 4.00 x 19 mm	III
5028938	5028938D	Coroflex ISAR NEO 2.00 x 24 mm	III
5028939	5028939D	Coroflex ISAR NEO 2.25 x 24 mm	III
5028940	5028940D	Coroflex ISAR NEO 2.50 x 24 mm	III
5028941	5028941D	Coroflex ISAR NEO 2.75 x 24 mm	III
5028942	5028942D	Coroflex ISAR NEO 3.00 x 24 mm	III
5028943	5028943D	Coroflex ISAR NEO 3.50 x 24 mm	III
5028944	5028944D	Coroflex ISAR NEO 4.00 x 24 mm	III
5028945	5028945D	Coroflex ISAR NEO 2.00 x 28 mm	III

<sup>1</sup> Manufacturing at B. Braun Melsungen AG, Vascular Systems Berlin, Germany. Date of CE mark: 2016-03-15

<sup>2</sup> Manufacturing at Aesculap Chifa Sp. z o. o., Poland. Date of CE mark of article numbers with Suffix D: 2021-02-18

<b>Art.-Nr. / REF No.<sup>1</sup></b>	<b>Art.-Nr. / REF No.<sup>2</sup></b>	<b>Article description</b>	<b>Klasse / Class</b>
5028946	5028946D	Coroflex ISAR NEO 2.25 x 28 mm	III
5028947	5028947D	Coroflex ISAR NEO 2.50 x 28 mm	III
5028948	5028948D	Coroflex ISAR NEO 2.75 x 28 mm	III
5028949	5028949D	Coroflex ISAR NEO 3.00 x 28 mm	III
5028950	5028950D	Coroflex ISAR NEO 3.50 x 28 mm	III
5028951	5028951D	Coroflex ISAR NEO 4.00 x 28 mm	III
5028952	5028952D	Coroflex ISAR NEO 2.00 x 32 mm	III
5028953	5028953D	Coroflex ISAR NEO 2.25 x 32 mm	III
5028954	5028954D	Coroflex ISAR NEO 2.50 x 32 mm	III
5028955	5028955D	Coroflex ISAR NEO 2.75 x 32 mm	III
5028956	5028956D	Coroflex ISAR NEO 3.00 x 32 mm	III
5028957	5028957D	Coroflex ISAR NEO 3.50 x 32 mm	III
5028958	5028958D	Coroflex ISAR NEO 4.00 x 32 mm	III
5028959	5028959D	Coroflex ISAR NEO 2.00 x 38 mm	III
5028960	5028960D	Coroflex ISAR NEO 2.25 x 38 mm	III
5028961	5028961D	Coroflex ISAR NEO 2.50 x 38 mm	III
5028962	5028962D	Coroflex ISAR NEO 2.75 x 38 mm	III
5028963	5028963D	Coroflex ISAR NEO 3.00 x 38 mm	III
5028964	5028964D	Coroflex ISAR NEO 3.50 x 38 mm	III
5028965	5028965D	Coroflex ISAR NEO 4.00 x 38 mm	III

Title: Coroflex ISAR NEO\_39.05.668\_DOC Initiator: Annesha ? Lahiri

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

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Meaning: Approve Document

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