

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**erklären in eigener Verantwortung,
dass das/die Produkt/e**VascuFlex 2-LOC / VascuFlex 3-LOC
VascuFlex 2-LOC NEO / VascuFlex 3-LOC NEO**selbstexpandierbare Nitinol-Stents
(Artikelnummern siehe Anlage I und II)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 IIb / Regel 8**Benannte Stelle**
Dekra Certification GmbH (ID-Nr. 0124)
Handwerkstraße 15, 70565 Stuttgart, Deutschland**Ausgestellte Bescheinigung(en):**
51342-16-02**Datum der ersten CE-Kennzeichnung**
2020-11-10 (Pull-back Variant)
2021-05-17 (NEO Variant)**Gültig bis**
2024-05-26Berlin, 2021-05-21
B. Braun Melsungen AGi. V. 
Dr. S. Vogelbein
Head of Quality Managementhereby declare in our own responsibility
that the product/s**VascuFlex 2-LOC / VascuFlex 3-LOC
VascuFlex 2-LOC NEO / VascuFlex 3-LOC NEO**self expanding stents made of Nitinol
(article numbers see attachment I and II)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according toannex II (excluding section 4)
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class IIb / Rule 8**Notified Body**
Dekra Certification GmbH (ID-No. 0124)
Handwerkstraße 15, 70565 Stuttgart, Germany**Certificate(s) issued:**
51342-16-02**Date of first CE-marking**
2020-11-10(Pull-back Variant)
2021-05-17 (NEO Variant)**Valid until**
2024-05-26Berlin, 2021-05-21
B. Braun Melsungen AGi. V. 
Dr. H. Schlicht
Head of Regulatory Affairs**Effective**

Anlage I / Attachment I: Vasculflex 2-LOC and Vasculflex 2-LOC NEO

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Klasse / Class	Date of first CE-marking
5506600	VascuFlex 2-LOC 6F 05mm x 30mm-130cm	IIb	2020-11-10
5506601	VascuFlex 2-LOC 6F 05mm x 40mm-130cm	IIb	2020-11-10
5506602	VascuFlex 2-LOC 6F 06mm x 30mm-130cm	IIb	2020-11-10
5506603	VascuFlex 2-LOC 6F 06mm x 40mm-130cm	IIb	2020-11-10
5506604	VascuFlex 2-LOC 6F 07mm x 30mm-130cm	IIb	2020-11-10
5506605	VascuFlex 2-LOC 6F 07mm x 40mm-130cm	IIb	2020-11-10
5506606	VascuFlex 2-LOC 6F 08mm x 30mm-130cm	IIb	2020-11-10
5506607	VascuFlex 2-LOC 6F 08mm x 40mm-130cm	IIb	2020-11-10
5506608	VascuFlex 2-LOC 6F 05mm x 30mm-80cm	IIb	2020-11-10
5506609	VascuFlex 2-LOC 6F 05mm x 40mm-80cm	IIb	2020-11-10
5506610	VascuFlex 2-LOC 6F 06mm x 30mm-80cm	IIb	2020-11-10
5506611	VascuFlex 2-LOC 6F 06mm x 40mm-80cm	IIb	2020-11-10
5506612	VascuFlex 2-LOC 6F 07mm x 30mm-80cm	IIb	2020-11-10
5506613	VascuFlex 2-LOC 6F 07mm x 40mm-80cm	IIb	2020-11-10
5506614	VascuFlex 2-LOC 6F 08mm x 30mm-80cm	IIb	2020-11-10
5506615	VascuFlex 2-LOC 6F 08mm x 40mm-80cm	IIb	2020-11-10

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Klasse / Class	Date of first CE-marking
5506600H	VascuFlex 2-LOC NEO 6F 05mm x 30mm-130cm	IIb	2021-05-17
5506601H	VascuFlex 2-LOC NEO 6F 05mm x 40mm-130cm	IIb	2021-05-17
5506602H	VascuFlex 2-LOC NEO 6F 06mm x 30mm-130cm	IIb	2021-05-17
5506603H	VascuFlex 2-LOC NEO 6F 06mm x 40mm-130cm	IIb	2021-05-17
5506604H	VascuFlex 2-LOC NEO 6F 07mm x 30mm-130cm	IIb	2021-05-17
5506605H	VascuFlex 2-LOC NEO 6F 07mm x 40mm-130cm	IIb	2021-05-17
5506606H	VascuFlex 2-LOC NEO 6F 08mm x 30mm-130cm	IIb	2021-05-17
5506607H	VascuFlex 2-LOC NEO 6F 08mm x 40mm-130cm	IIb	2021-05-17
5506608H	VascuFlex 2-LOC NEO 6F 05mm x 30mm-80cm	IIb	2021-05-17
5506609H	VascuFlex 2-LOC NEO 6F 05mm x 40mm-80cm	IIb	2021-05-17
5506610H	VascuFlex 2-LOC NEO 6F 06mm x 30mm-80cm	IIb	2021-05-17
5506611H	VascuFlex 2-LOC NEO 6F 06mm x 40mm-80cm	IIb	2021-05-17
5506612H	VascuFlex 2-LOC NEO 6F 07mm x 30mm-80cm	IIb	2021-05-17
5506613H	VascuFlex 2-LOC NEO 6F 07mm x 40mm-80cm	IIb	2021-05-17
5506614H	VascuFlex 2-LOC NEO 6F 08mm x 30mm-80cm	IIb	2021-05-17
5506615H	VascuFlex 2-LOC NEO 6F 08mm x 40mm-80cm	IIb	2021-05-17

Anlage II / Attachment II: VascuFlex 3-LOC and VascuFlex 3-LOC NEO

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Klasse / Class	Date of first CE-marking
5506620	VascuFlex 3-LOC 6F 05mm x 30mm-130cm	IIb	2020-11-10
5506621	VascuFlex 3-LOC 6F 05mm x 40mm-130cm	IIb	2020-11-10
5506622	VascuFlex 3-LOC 6F 06mm x 30mm-130cm	IIb	2020-11-10
5506623	VascuFlex 3-LOC 6F 06mm x 40mm-130cm	IIb	2020-11-10
5506624	VascuFlex 3-LOC 6F 07mm x 30mm-130cm	IIb	2020-11-10
5506625	VascuFlex 3-LOC 6F 07mm x 40mm-130cm	IIb	2020-11-10
5506626	VascuFlex 3-LOC 6F 08mm x 30mm-130cm	IIb	2020-11-10
5506627	VascuFlex 3-LOC 6F 08mm x 40mm-130cm	IIb	2020-11-10
5506628	VascuFlex 3-LOC 6F 05mm x 30mm-80cm	IIb	2020-11-10
5506629	VascuFlex 3-LOC 6F 05mm x 40mm-80cm	IIb	2020-11-10
5506630	VascuFlex 3-LOC 6F 06mm x 30mm-80cm	IIb	2020-11-10
5506631	VascuFlex 3-LOC 6F 06mm x 40mm-80cm	IIb	2020-11-10
5506632	VascuFlex 3-LOC 6F 07mm x 30mm-80cm	IIb	2020-11-10
5506633	VascuFlex 3-LOC 6F 07mm x 40mm-80cm	IIb	2020-11-10
5506634	VascuFlex 3-LOC 6F 08mm x 30mm-80cm	IIb	2020-11-10
5506635	VascuFlex 3-LOC 6F 08mm x 40mm-80cm	IIb	2020-11-10

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Klasse / Class	Date of first CE-marking
5506620H	VascuFlex 3-LOC NEO 6F 05mm x 30mm-130cm	IIb	2021-05-17
5506621H	VascuFlex 3-LOC NEO 6F 05mm x 40mm-130cm	IIb	2021-05-17
5506622H	VascuFlex 3-LOC NEO 6F 06mm x 30mm-130cm	IIb	2021-05-17
5506623H	VascuFlex 3-LOC NEO 6F 06mm x 40mm-130cm	IIb	2021-05-17
5506624H	VascuFlex 3-LOC NEO 6F 07mm x 30mm-130cm	IIb	2021-05-17
5506625H	VascuFlex 3-LOC NEO 6F 07mm x 40mm-130cm	IIb	2021-05-17
5506626H	VascuFlex 3-LOC NEO 6F 08mm x 30mm-130cm	IIb	2021-05-17
5506627H	VascuFlex 3-LOC NEO 6F 08mm x 40mm-130cm	IIb	2021-05-17
5506628H	VascuFlex 3-LOC NEO 6F 05mm x 30mm-80cm	IIb	2021-05-17
5506629H	VascuFlex 3-LOC NEO 6F 05mm x 40mm-80cm	IIb	2021-05-17
5506630H	VascuFlex 3-LOC NEO 6F 06mm x 30mm-80cm	IIb	2021-05-17
5506631H	VascuFlex 3-LOC NEO 6F 06mm x 40mm-80cm	IIb	2021-05-17
5506632H	VascuFlex 3-LOC NEO 6F 07mm x 30mm-80cm	IIb	2021-05-17
5506633H	VascuFlex 3-LOC NEO 6F 07mm x 40mm-80cm	IIb	2021-05-17
5506634H	VascuFlex 3-LOC NEO 6F 08mm x 30mm-80cm	IIb	2021-05-17
5506635H	VascuFlex 3-LOC NEO 6F 08mm x 40mm-80cm	IIb	2021-05-17

Title: Vasculflex 2-LOC_3-LOC_39.05.669_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: Tuesday, 06 July 2021, 17:51 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Schlicht, Henning (schlhgde)
Title: Head of Regulatory Affairs
Date: Wednesday, 07 July 2021, 09:55 W. Europe Daylight Time
Meaning: Approve Document
