

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**erklären in eigener Verantwortung,
dass das/die Produkt/ehereby declare in our own responsibility
that the product/s**VascuFlex Multi-LOC/VascuFlex Multi-LOC NEO****VascuFlex Multi-LOC/VascuFlex Multi-LOC NEO**selbstexpandierbare Nitinol-Stents
(Artikelnummern siehe Anlage I und II)self expanding stents made of Nitinol
(article numbers see attachment I and II)mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

is/are in compliance with the following directive

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EGCouncil Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC**Konformitätsbewertungsverfahren****Conformity Assessment Procedure**nach
Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinieaccording to
annex II (excluding section 4)
of the Council Directive named above**Klassifizierung****Classification**gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIb / Regel 8according to annex IX of the
Council Directive named above
Class IIb / Rule 8**Benannte Stelle****Notified Body**Dekra Certification GmbH (ID-Nr. 0124)
Handwerkstraße 15, 70565 Stuttgart, DeutschlandDekra Certification GmbH (ID-No. 0124)
Handwerkstraße 15, 70565 Stuttgart, Germany**Ausgestellte Bescheinigung(en):**

51342-16-02

Certificate(s) issued:

51342-16-02

Datum der ersten CE-Kennzeichnung2015-10-29 (Pull back Variant)
2021-05-17 (NEO Variant)**Date of first CE-marking**2015-10-29 (Pull-back Variant)
2021-05-17 (NEO Variant)**Gültig bis**

2024-05-26

Valid until

2024-05-26

Berlin, 2021-05-21

Berlin, 2021-05-21

B. Braun Melsungen AG

B. Braun Melsungen AG

i. V.

Dr. S. Vogelbein

Head of Quality Management

i. V.

Dr. H. Schlicht

Head of Regulatory Affairs

Form: SA-DE03-M-5-1-12-000-4-D-DE/EN

Anlage I / Attachment I: VascuFlex Multi-LOC

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Klasse / Class	Datum der CE-Kennzeichnung / Date of CE mark
5506650	VascuFlex Multi-LOC 6F 05mm x 100mm-130cm	IIb	2015-10-29
5506651	VascuFlex Multi-LOC 6F 06mm x 100mm-130cm	IIb	2015-10-29
5506652	VascuFlex Multi-LOC 6F 07mm x 100mm-130cm	IIb	2015-10-29
5506653	VascuFlex Multi-LOC 6F 08mm x 100mm-130cm	IIb	2015-10-29
5506654	VascuFlex Multi-LOC 6F 05mm x 100mm-80cm	IIb	2015-10-29
5506655	VascuFlex Multi-LOC 6F 06mm x 100mm-80cm	IIb	2015-10-29
5506656	VascuFlex Multi-LOC 6F 07mm x 100mm-80cm	IIb	2015-10-29
5506657	VascuFlex Multi-LOC 6F 08mm x 100mm-80cm	IIb	2015-10-29

Anlage II / Attachment II: VascuFlex Multi-LOC NEO

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Klasse / Class	Datum der CE-Kennzeichnung / Date of CE mark
5506650H	VascuFlex Multi-LOC NEO 6F 05 x 100mm-130cm	IIb	2021-05-17
5506651H	VascuFlex Multi-LOC NEO 6F 06 x 100mm-130cm	IIb	2021-05-17
5506652H	VascuFlex Multi-LOC NEO 6F 07 x 100mm-130cm	IIb	2021-05-17
5506653H	VascuFlex Multi-LOC NEO 6F 08 x 100mm-130cm	IIb	2021-05-17
5506654H	VascuFlex Multi-LOC NEO 6F 05 x 100mm-80cm	IIb	2021-05-17
5506655H	VascuFlex Multi-LOC NEO 6F 06 x 100mm-80cm	IIb	2021-05-17
5506656H	VascuFlex Multi-LOC NEO 6F 07 x 100mm-80cm	IIb	2021-05-17
5506657H	VascuFlex Multi-LOC NEO 6F 08 x 100mm-80cm	IIb	2021-05-17

Title: Vasculflex Multi-LOC_39.05.670_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, 17:56 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Schlicht, Henning (schlhgde)
Title: Head of Regulatory Affairs
Date: Wednesday, 07 July 2021, 09:56 W. Europe Daylight Time
Meaning: Approve Document
