

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**erklären in eigener Verantwortung,
dass das/die Produkt/e**SeQuent NEO NC**
PTCA-Katheter
(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 / Regel 6**Benannte Stelle**
DEKRA Certification GmbH (ID-Nr. 0124)
Handwerkstraße 15, 70565 Stuttgart, Deutschland**Ausgestellte Bescheinigung(en):**
51342-16-02
51342-23-H0**Datum der ersten CE-Kennzeichnung**
2018-06-26**Gültig bis**
2023-06-25hereby declare in our own responsibility
that the product/s**SeQuent NEO NC**
PTCA-Catheter
(article numbers see attachment I)

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 to annex II, II.4
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class III / Rule 6**Notified Body**
DEKRA Certification GmbH (ID-No. 0124)
Handwerkstraße 15, 70565 Stuttgart, Germany**Certificate(s) issued:**
51342-16-02
51342-23-H0**Date of first CE-marking**
2018-06-26**Valid until**
2023-06-25

Berlin, 2019-11-21

B. Braun Melsungen AG

i. V.


Dr. D. Schauer
Head of Quality Management CoE VS

Berlin, 2019-11-21

B. Braun Melsungen AG

i. V.


Dr. H. Schlicht
Head of Regulatory Affairs

Effective

Anlage I / Attachment I

Art.-Nr. REF No.	Artikelbezeichnung	Article description	Klasse Class
5023900	SeQuent NEO NC 2.0 x 8 mm	SeQuent NEO NC 2.0 x 8 mm	III
5023901	SeQuent NEO NC 2.25 x 8 mm	SeQuent NEO NC 2.25 x 8 mm	III
5023902	SeQuent NEO NC 2.5 x 8 mm	SeQuent NEO NC 2.5 x 8 mm	III
5023903	SeQuent NEO NC 2.75 x 8 mm	SeQuent NEO NC 2.75 x 8 mm	III
5023904	SeQuent NEO NC 3.0 x 8 mm	SeQuent NEO NC 3.0 x 8 mm	III
5023905	SeQuent NEO NC 3.25 x 8 mm	SeQuent NEO NC 3.25 x 8 mm	III
5023906	SeQuent NEO NC 3.5 x 8 mm	SeQuent NEO NC 3.5 x 8 mm	III
5023907	SeQuent NEO NC 4.0 x 8 mm	SeQuent NEO NC 4.0 x 8 mm	III
5023908	SeQuent NEO NC 4.5 x 8 mm	SeQuent NEO NC 4.5 x 8 mm	III
5023910	SeQuent NEO NC 2.0 x 10 mm	SeQuent NEO NC 2.0 x 10 mm	III
5023911	SeQuent NEO NC 2.25 x 10 mm	SeQuent NEO NC 2.25 x 10 mm	III
5023912	SeQuent NEO NC 2.5 x 10 mm	SeQuent NEO NC 2.5 x 10 mm	III
5023913	SeQuent NEO NC 2.75 x 10 mm	SeQuent NEO NC 2.75 x 10 mm	III
5023914	SeQuent NEO NC 3.0 x 10 mm	SeQuent NEO NC 3.0 x 10 mm	III
5023915	SeQuent NEO NC 3.25 x 10 mm	SeQuent NEO NC 3.25 x 10 mm	III
5023916	SeQuent NEO NC 3.5 x 10 mm	SeQuent NEO NC 3.5 x 10 mm	III
5023917	SeQuent NEO NC 4.0 x 10 mm	SeQuent NEO NC 4.0 x 10 mm	III
5023918	SeQuent NEO NC 4.5 x 10 mm	SeQuent NEO NC 4.5 x 10 mm	III
5023920	SeQuent NEO NC 2.0 x 12 mm	SeQuent NEO NC 2.0 x 12 mm	III
5023921	SeQuent NEO NC 2.25 x 12 mm	SeQuent NEO NC 2.25 x 12 mm	III
5023922	SeQuent NEO NC 2.5 x 12 mm	SeQuent NEO NC 2.5 x 12 mm	III
5023923	SeQuent NEO NC 2.75 x 12 mm	SeQuent NEO NC 2.75 x 12 mm	III
5023924	SeQuent NEO NC 3.0 x 12 mm	SeQuent NEO NC 3.0 x 12 mm	III
5023925	SeQuent NEO NC 3.25 x 12 mm	SeQuent NEO NC 3.25 x 12 mm	III
5023926	SeQuent NEO NC 3.5 x 12 mm	SeQuent NEO NC 3.5 x 12 mm	III
5023927	SeQuent NEO NC 4.0 x 12 mm	SeQuent NEO NC 4.0 x 12 mm	III
5023928	SeQuent NEO NC 4.5 x 12 mm	SeQuent NEO NC 4.5 x 12 mm	III
5023930	SeQuent NEO NC 2.0 x 15 mm	SeQuent NEO NC 2.0 x 15 mm	III
5023931	SeQuent NEO NC 2.25 x 15 mm	SeQuent NEO NC 2.25 x 15 mm	III
5023932	SeQuent NEO NC 2.5 x 15 mm	SeQuent NEO NC 2.5 x 15 mm	III
5023933	SeQuent NEO NC 2.75 x 15 mm	SeQuent NEO NC 2.75 x 15 mm	III
5023934	SeQuent NEO NC 3.0 x 15 mm	SeQuent NEO NC 3.0 x 15 mm	III
5023935	SeQuent NEO NC 3.25 x 15 mm	SeQuent NEO NC 3.25 x 15 mm	III
5023936	SeQuent NEO NC 3.5 x 15 mm	SeQuent NEO NC 3.5 x 15 mm	III
5023937	SeQuent NEO NC 4.0 x 15 mm	SeQuent NEO NC 4.0 x 15 mm	III
5023938	SeQuent NEO NC 4.5 x 15 mm	SeQuent NEO NC 4.5 x 15 mm	III
5023940	SeQuent NEO NC 2.0 x 20 mm	SeQuent NEO NC 2.0 x 20 mm	III
5023941	SeQuent NEO NC 2.25 x 20 mm	SeQuent NEO NC 2.25 x 20 mm	III
5023942	SeQuent NEO NC 2.5 x 20 mm	SeQuent NEO NC 2.5 x 20 mm	III

Art.-Nr. REF No.	Artikelbezeichnung	Article description	Klasse Class
5023943	SeQuent NEO NC 2.75 x 20 mm	SeQuent NEO NC 2.75 x 20 mm	III
5023944	SeQuent NEO NC 3.0 x 20 mm	SeQuent NEO NC 3.0 x 20 mm	III
5023945	SeQuent NEO NC 3.25 x 20 mm	SeQuent NEO NC 3.25 x 20 mm	III
5023946	SeQuent NEO NC 3.5 x 20 mm	SeQuent NEO NC 3.5 x 20 mm	III
5023947	SeQuent NEO NC 4.0 x 20 mm	SeQuent NEO NC 4.0 x 20 mm	III
5023948	SeQuent NEO NC 4.5 x 20 mm	SeQuent NEO NC 4.5 x 20 mm	III
5023960	SeQuent NEO NC 2.0 x 30 mm	SeQuent NEO NC 2.0 x 30 mm	III
5023961	SeQuent NEO NC 2.25 x 30 mm	SeQuent NEO NC 2.25 x 30 mm	III
5023962	SeQuent NEO NC 2.5 x 30 mm	SeQuent NEO NC 2.5 x 30 mm	III
5023963	SeQuent NEO NC 2.75 x 30 mm	SeQuent NEO NC 2.75 x 30 mm	III
5023964	SeQuent NEO NC 3.0 x 30 mm	SeQuent NEO NC 3.0 x 30 mm	III
5023965	SeQuent NEO NC 3.25 x 30 mm	SeQuent NEO NC 3.25 x 30 mm	III
5023966	SeQuent NEO NC 3.5 x 30 mm	SeQuent NEO NC 3.5 x 30 mm	III
5023967	SeQuent NEO NC 4.0 x 30 mm	SeQuent NEO NC 4.0 x 30 mm	III
5023968	SeQuent NEO NC 4.5 x 30 mm	SeQuent NEO NC 4.5 x 30 mm	III

Title: SeQuent NEO NC_39.05.665_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: Document signed as Author

UserName: Schlicht, Henning (schlhgde)
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Date: Wednesday, 12 May 2021, 14:33 W. Europe Daylight Time
Meaning: Approve Document
