

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**SeQuent SCB**
PTCA-Katheter
(Artikelnummern siehe Anlage I)**SeQuent SCB**
PTCA-Catheter
(article numbers see attachment I)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**
nach Anhang II, II.4
der oben genannten Richtlinie**Conformity Assessment Procedure**
according to annex II, II.4
of the Council Directive named above**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse III / Regel 13**Classification**
according to annex IX of the
Council Directive named above
Class III / Rule 13**Benannte Stelle**
DEKRA Certification GmbH (ID-Nr. 0124)
Handwerkstraße 15, 70565 Stuttgart, Deutschland**Notified Body**
DEKRA Certification GmbH (ID-No. 0124)
Handwerkstraße 15, 70565 Stuttgart, Germany**Ausgestellte Bescheinigung(en):**
51342-16-02
51342-23-F1**Certificate(s) issued:**
51342-16-02
51342-23-F1**Datum der ersten CE-Kennzeichnung**
2016-10-31**Date of first CE-marking**
2016-10-31**Gültig bis**
2024-05-26**Valid until**
2024-05-26

Berlin, 2021-04-20

Berlin, 2021-04-20

B. Braun Melsungen AG

B. Braun Melsungen AG

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Dr. S. Vogelbein
Head of Quality ManagementDr. H. Schlicht
Head of Regulatory Affairs

Effective

Anlage I / Annex I

Art.-Nr. / REF No.¹	Art.-Nr. / REF No.²	Article description	Klasse / Class
5024250	5024250D	SeQuent SCB 2.0 x 10 mm	III
5024251	5024251D	SeQuent SCB 2.25 x 10 mm	III
5024252	5024252D	SeQuent SCB 2.5 x 10 mm	III
5024253	5024253D	SeQuent SCB 2.75 x 10 mm	III
5024254	5024254D	SeQuent SCB 3.0 x 10 mm	III
5024255	5024255D	SeQuent SCB 3.5 x 10 mm	III
5024256	5024256D	SeQuent SCB 4.0 x 10 mm	III
5024257	5024257D	SeQuent SCB 2.0 x 15 mm	III
5024258	5024258D	SeQuent SCB 2.25 x 15 mm	III
5024259	5024259D	SeQuent SCB 2.5 x 15 mm	III
5024260	5024260D	SeQuent SCB 2.75 x 15 mm	III
5024261	5024261D	SeQuent SCB 3.0 x 15 mm	III
5024262	5024262D	SeQuent SCB 3.5 x 15 mm	III
5024263	5024263D	SeQuent SCB 4.0 x 15 mm	III
5024264	5024264D	SeQuent SCB 2.0 x 20 mm	III
5024265	5024265D	SeQuent SCB 2.25 x 20 mm	III
5024266	5024266D	SeQuent SCB 2.5 x 20 mm	III
5024267	5024267D	SeQuent SCB 2.75 x 20 mm	III
5024268	5024268D	SeQuent SCB 3.0 x 20 mm	III
5024269	5024269D	SeQuent SCB 3.5 x 20 mm	III
5024270	5024270D	SeQuent SCB 4.0 x 20 mm	III
5024271	5024271D	SeQuent SCB 2.0 x 25 mm	III
5024272	5024272D	SeQuent SCB 2.25 x 25 mm	III
5024273	5024273D	SeQuent SCB 2.5 x 25 mm	III
5024274	5024274D	SeQuent SCB 2.75 x 25 mm	III
5024275	5024275D	SeQuent SCB 3.0 x 25 mm	III
5024276	5024276D	SeQuent SCB 3.5 x 25 mm	III
5024277	5024277D	SeQuent SCB 4.0 x 25 mm	III
5024278	5024278D	SeQuent SCB 2.0 x 30 mm	III
5024279	5024279D	SeQuent SCB 2.25 x 30 mm	III
5024280	5024280D	SeQuent SCB 2.5 x 30 mm	III
5024281	5024281D	SeQuent SCB 2.75 x 30 mm	III
5024282	5024282D	SeQuent SCB 3.0 x 30 mm	III
5024283	5024283D	SeQuent SCB 3.5 x 30 mm	III
5024284	5024284D	SeQuent SCB 4.0 x 30 mm	III
5024285	5024285D	SeQuent SCB 2.0 x 35 mm	III

¹ Manufacturing at B. Braun Melsungen AG, Vascular Systems Berlin, Germany. Date of CE mark: 2016-10-31

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

Art.-Nr. / REF No.¹	Art.-Nr. / REF No.²	Article description	Klasse / Class
5024286	5024286D	SeQuent SCB 2.25 x 35 mm	III
5024287	5024287D	SeQuent SCB 2.5 x 35 mm	III
5024288	5024288D	SeQuent SCB 2.75 x 35 mm	III
5024289	5024289D	SeQuent SCB 3.0 x 35 mm	III
5024290	5024290D	SeQuent SCB 3.5 x 35 mm	III
5024291	5024291D	SeQuent SCB 4.0 x 35 mm	III
5024292	5024292D	SeQuent SCB 2.0 x 40 mm	III
5024293	5024293D	SeQuent SCB 2.25 x 40 mm	III
5024294	5024294D	SeQuent SCB 2.5 x 40 mm	III
5024295	5024295D	SeQuent SCB 2.75 x 40 mm	III
5024296	5024296D	SeQuent SCB 3.0 x 40 mm	III
5024297	5024297D	SeQuent SCB 3.5 x 40 mm	III
5024298	5024298D	SeQuent SCB 4.0 x 40 mm	III

Title: SeQuent SCB_39.05.662_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)
Title: Head of Regulatory Affairs
Date: Wednesday, 12 May 2021, 14:34 W. Europe Daylight Time
Meaning: Approve Document
