

Wir

We

**B. Braun Melsungen AG  
Carl-Braun-Straße 1  
34212 Melsungen  
Deutschland/Germany**erklären in eigener Verantwortung,  
dass das/die Produkt/e**SeQuent Please NEO**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, 13**Benannte Stelle**  
TÜV SÜD Product Service GmbH (ID-Nr. 0123)  
Ridlerstraße 65, 80339 München, Deutschland**Ausgestellte Bescheinigung(en):**  
G1 012974 0608 Rev. 00  
G7 012974 0604 Rev.01**Datum der ersten CE-Kennzeichnung**  
2015-09-17**Gültig bis**  
2024-05-26

Berlin, 2020-05-19

B. Braun Melsungen AG

i. A.

Dr. S. Vogelbein  
Head of Quality Management CoE VShereby declare in our own responsibility  
that the product/s**SeQuent Please NEO**PTCA-Catheter  
(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 / Rule 6, 13**Notified Body**  
TÜV SÜD Product Service GmbH (ID-No. 0123)  
Ridlerstraße 65, 80339 Munich, Germany**Certificate(s) issued:**  
G1 012974 0608 Rev. 00  
G7 012974 0604 Rev.01**Date of first CE-marking**  
2015-09-17**Valid until**  
2024-05-26

Berlin, 2020-05-19

B. Braun Melsungen AG

i. V.

Dr. H. Schlicht  
Head of Regulatory Affairs

**Anlage I / Attachment I**

<b>Art.-Nr. / REF No.<sup>1</sup></b>	<b>Art.-Nr. / REF No.<sup>2</sup></b>	<b>Artikelbezeichnung / Article description</b>	<b>Klasse / Class</b>
5023200	5023200A	SeQuent Please NEO 2.0 x 10 mm	III
5023201	5023201A	SeQuent Please NEO 2.25 x 10 mm	III
5023202	5023202A	SeQuent Please NEO 2.5 x 10 mm	III
5023203	5023203A	SeQuent Please NEO 2.75 x 10 mm	III
5023204	5023204A	SeQuent Please NEO 3.0 x 10 mm	III
5023206	5023206A	SeQuent Please NEO 3.5 x 10 mm	III
5023207	5023207A	SeQuent Please NEO 4.0 x 10 mm	III
5023210	5023210A	SeQuent Please NEO 2.0 x 15 mm	III
5023211	5023211A	SeQuent Please NEO 2.25 x 15 mm	III
5023212	5023212A	SeQuent Please NEO 2.5 x 15 mm	III
5023213	5023213A	SeQuent Please NEO 2.75 x 15 mm	III
5023214	5023214A	SeQuent Please NEO 3.0 x 15 mm	III
5023216	5023216A	SeQuent Please NEO 3.5 x 15 mm	III
5023217	5023217A	SeQuent Please NEO 4.0 x 15 mm	III
5023220	5023220A	SeQuent Please NEO 2.0 x 20 mm	III
5023221	5023221A	SeQuent Please NEO 2.25 x 20 mm	III
5023222	5023222A	SeQuent Please NEO 2.5 x 20 mm	III
5023223	5023223A	SeQuent Please NEO 2.75 x 20 mm	III
5023224	5023224A	SeQuent Please NEO 3.0 x 20 mm	III
5023226	5023226A	SeQuent Please NEO 3.5 x 20 mm	III
5023227	5023227A	SeQuent Please NEO 4.0 x 20 mm	III
5023230	5023230A	SeQuent Please NEO 2.0 x 25 mm	III
5023231	5023231A	SeQuent Please NEO 2.25 x 25 mm	III
5023232	5023232A	SeQuent Please NEO 2.5 x 25 mm	III
5023233	5023233A	SeQuent Please NEO 2.75 x 25 mm	III
5023234	5023234A	SeQuent Please NEO 3.0 x 25 mm	III
5023236	5023236A	SeQuent Please NEO 3.5 x 25 mm	III
5023237	5023237A	SeQuent Please NEO 4.0 x 25 mm	III
5023240	5023240A	SeQuent Please NEO 2.0 x 30 mm	III
5023241	5023241A	SeQuent Please NEO 2.25 x 30 mm	III
5023242	5023242A	SeQuent Please NEO 2.5 x 30 mm	III
5023243	5023243A	SeQuent Please NEO 2.75 x 30 mm	III
5023244	5023244A	SeQuent Please NEO 3.0 x 30 mm	III
5023246	5023246A	SeQuent Please NEO 3.5 x 30 mm	III
5023247	5023247A	SeQuent Please NEO 4.0 x 30 mm	III
5023250	5023250A	SeQuent Please NEO 2.0 x 35 mm	III
5023251	5023251A	SeQuent Please NEO 2.25 x 35 mm	III
5023252	5023252A	SeQuent Please NEO 2.5 x 35 mm	III
5023253	5023253A	SeQuent Please NEO 2.75 x 35 mm	III
5023254	5023254A	SeQuent Please NEO 3.0 x 35 mm	III
5023256	5023256A	SeQuent Please NEO 3.5 x 35 mm	III

<sup>1</sup> Manufactured at the manufacturing site B. Braun Melsungen AG, Vascular Systems Berlin, Germany.

<sup>2</sup> Product may contain assemblies manufactured at the manufacturing site B. Braun Medical Suzhou, China.

<b>Art.-Nr. / REF No.<sup>1</sup></b>	<b>Art.-Nr. / REF No.<sup>2</sup></b>	<b>Artikelbezeichnung / Article description</b>	<b>Klasse / Class</b>
5023257	5023257A	SeQuent Please NEO 4.0 x 35 mm	III
5023260	5023260A	SeQuent Please NEO 2.0 x 40 mm	III
5023261	5023261A	SeQuent Please NEO 2.25 x 40 mm	III
5023262	5023262A	SeQuent Please NEO 2.5 x 40 mm	III
5023263	5023263A	SeQuent Please NEO 2.75 x 40 mm	III
5023264	5023264A	SeQuent Please NEO 3.0 x 40 mm	III
5023266	5023266A	SeQuent Please NEO 3.5 x 40 mm	III
5023267	5023267A	SeQuent Please NEO 4.0 x 40 mm	III

Effective

Title: SeQuent Please Neo 39.05.661\_DOC Initiator: Annesha ? Lahiri

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Meaning: Approve Document

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