Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
12974	713211265 | 713263785	medical_devices@tuvsud.com	n/a	2025-05-16	Page **1** of **5**

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 012974 0659 Rev. 00

Reference: 713211265 | 713263785

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following.

SRN Number: DE-MF-000000201

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 012974 0659 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,

16th May 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 916457

Sabine Osterhues
Project Handler (PH)

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 778941

Florian Grentzebach
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name (under MDR application)	**Article Number** (under MDR application)	**If the MDR device is a substitute device, identification of the corresponding MDD/ AIMDD device**	**Basic UDI-DI** (under MDR application)	**MDR Device classification** (as proposed by the manufacturer and verified during application review)	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
SeQuent Neo 1.25 x 10 mm	5021711	n/a	403923900000135228	Class III	☒ Certification as follows: G7 012974 0603 Rev. 02 NB 0123 G1 012974 0608 Rev 00 NB 0123
SeQuent Neo 1.5 x 10 mm	5021712				
SeQuent Neo 2.0 x 10 mm	5021713				
SeQuent Neo 2.25 x 10 mm	5021714				
SeQuent Neo 2.5 x 10 mm	5021715				
SeQuent Neo 2.75 x 10 mm	5021716				
SeQuent Neo 3.0 x 10 mm	5021717				
SeQuent Neo 3.5 x 10 mm	5021718				
SeQuent Neo 4.0 x 10 mm	5021719				
SeQuent Neo 1.25 x 15 mm	5021721				
SeQuent Neo 1.5 x 15 mm	5021722				
SeQuent Neo 2.0 x 15 mm	5021723				
SeQuent Neo 2.25 x 15 mm	5021724				
SeQuent Neo 2.5 x 15 mm	5021725				
SeQuent Neo 2.75 x 15 mm	5021726				
SeQuent Neo 3.0 x 15 mm	5021727				
SeQuent Neo 3.5 x 15 mm	5021728				
SeQuent Neo 4.0 x 15 mm	5021729				
SeQuent Neo 1.25 x 20 mm	5021731				
SeQuent Neo 1.5 x 20 mm	5021732				
SeQuent Neo 2.0 x 20 mm	5021733				
SeQuent Neo 2.25 x 20 mm	5021734				
SeQuent Neo 2.5 x 20 mm	5021735				
SeQuent Neo 2.75 x 20 mm	5021736				
SeQuent Neo 3.0 x 20 mm	5021737				
SeQuent Neo 3.5 x 20 mm	5021738				
SeQuent Neo 4.0 x 20 mm	5021739				
SeQuent Neo 2.0 x 25 mm	5021743				
SeQuent Neo 2.25 x 25 mm	5021744				
SeQuent Neo 2.5 x 25 mm	5021745				
SeQuent Neo 2.75 x 25 mm	5021746				
SeQuent Neo 3.0 x 25 mm	5021747				
SeQuent Neo 3.5 x 25 mm	5021748				
SeQuent Neo 4.0 x 25 mm	5021749				
SeQuent Neo 2.0 x 30 mm	5021753				
SeQuent Neo 2.25 x 30 mm	5021754				
SeQuent Neo 2.5 x 30 mm	5021755				
SeQuent Neo 2.75 x 30 mm	5021756				
SeQuent Neo 3.0 x 30 mm	5021757				
SeQuent Neo 3.5 x 30 mm	5021758				
SeQuent Neo 4.0 x 30 mm	5021759				
SeQuent Neo 1.25 x 10 mm	5021711D				
SeQuent Neo 1.5 x 10 mm	5021712D				
SeQuent Neo 2.0 x 10 mm	5021713D				
SeQuent Neo 2.25 x 10 mm	5021714D				
SeQuent Neo 2.5 x 10 mm	5021715D				
SeQuent Neo 2.75 x 10 mm	5021716D				
SeQuent Neo 3.0 x 10 mm	5021717D				
SeQuent Neo 3.5 x 10 mm	5021718D				
SeQuent Neo 4.0 x 10 mm	5021719D				
SeQuent Neo 1.25 x 15 mm	5021721D				
SeQuent Neo 1.5 x 15 mm	5021722D				

Device name (under MDR application)	**Article Number** (under MDR application)	**If the MDR device is a substitute device, identification of the corresponding MDD/ AIMDD device**	**Basic UDI-DI** (under MDR application)	**MDR Device classification** (as proposed by the manufacturer and verified during application review)	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
SeQuent Neo 2.0 x 15 mm	5021723D				
SeQuent Neo 2.25 x 15 mm	5021724D				
SeQuent Neo 2.5 x 15 mm	5021725D				
SeQuent Neo 2.75 x 15 mm	5021726D				
SeQuent Neo 3.0 x 15 mm	5021727D				
SeQuent Neo 3.5 x 15 mm	5021728D				
SeQuent Neo 4.0 x 15 mm	5021729D				
SeQuent Neo 1.25 x 20 mm	5021731D				
SeQuent Neo 1.5 x 20 mm	5021732D				
SeQuent Neo 2.0 x 20 mm	5021733D				
SeQuent Neo 2.25 x 20 mm	5021734D				
SeQuent Neo 2.5 x 20 mm	5021735D				
SeQuent Neo 2.75 x 20 mm	5021736D				
SeQuent Neo 3.0 x 20 mm	5021737D				
SeQuent Neo 3.5 x 20 mm	5021738D				
SeQuent Neo 4.0 x 20 mm	5021739D				
SeQuent Neo 2.0 x 25 mm	5021743D				
SeQuent Neo 2.25 x 25 mm	5021744D				
SeQuent Neo 2.5 x 25 mm	5021745D				
SeQuent Neo 2.75 x 25 mm	5021746D				
SeQuent Neo 3.0 x 25 mm	5021747D				
SeQuent Neo 3.5 x 25 mm	5021748D				
SeQuent Neo 4.0 x 25 mm	5021749D				
SeQuent Neo 2.0 x 30 mm	5021753D				
SeQuent Neo 2.25 x 30 mm	5021754D				
SeQuent Neo 2.5 x 30 mm	5021755D				
SeQuent Neo 2.75 x 30 mm	5021756D				
SeQuent Neo 3.0 x 30 mm	5021757D				
SeQuent Neo 3.5 x 30 mm	5021758D				
SeQuent Neo 4.0 x 30 mm	5021759D				

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive: N/A

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified during application review)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**

Confirmation Letter Version History

Revision	Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
00	2024/05/16	713211265 | 713263785	Initial issue