



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	713331199 / 713263785	medical_devices@tuvsud.com	N/A	2024-07-09	1 of 8

**TÜV SÜD Product Service GmbH  
Confirmation Letter  
CL 012974 0669 Rev. 00**

**Reference: 713331199 / 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:

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.

**Registered Office: Munich**  
Trade Register Munich HRB 85 742  
UniCredit Bank AG · BIC HYVEDEMMXXX  
IBAN DE13 7002 0270 0048 8522 11  
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(Germany) at tuvsud.com/imprint

**Supervisory Board:**  
Holger Lindner (Chairman)  
**Board of Management:**  
Walter Reithmaier (CEO)  
Patrick van Welij

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

tuvsud.com/ps  
Hotline: +49 89 50084-744

**TÜV®**

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\\_0669\\_Rev.\\_00](http://www.tuvsud.com/ps-cert?q=cert:CL_012974_0669_Rev._00)

In case of inquiries please contact [medical\\_devices@tuvsud.com](mailto:medical_devices@tuvsud.com).

On behalf of the Notified Body TÜV SÜD Product Service GmbH,  
2024-07-09

TÜV SÜD Product Service GmbH  
Medical and Health Services



SIGN-ID 916294  
16.05.2024

Dr. Annemarie Stroh  
Project Handler (PH)

TÜV SÜD Product Service GmbH  
Medical and Health Services



SIGN-ID 803172

Florian Grentz bach  
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 NC 2.0 x 8 mm	5023900	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.25 x 8 mm	5023901	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.5 x 8 mm	5023902	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.75 x 8 mm	5023903	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.0 x 8 mm	5023904	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.25 x 8 mm	5023905	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.5 x 8 mm	5023906	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.0 x 8 mm	5023907	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.5 x 8 mm	5023908	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.0 x 10 mm	5023910	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.25 x 10 mm	5023911	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.5 x 10 mm	5023912	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.75 x 10 mm	5023913	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124

<b>Device name</b> (under MDR application)	<b>Article number</b> (under MDR application)	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>Basic UDI-DI</b> (under MDR application)	<b>MDR Device classification</b> (as proposed by the manufacturer and verified during application review)	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
SeQuent NEO NC 3.0 x 10 mm	5023914	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.25 x 10 mm	5023915	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.5 x 10 mm	5023916	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.0 x 10 mm	5023917	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.5 x 10 mm	5023918	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.0 x 12 mm	5023920	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.25 x 12 mm	5023921	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.5 x 12 mm	5023922	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.75 x 12 mm	5023923	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.0 x 12 mm	5023924	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.25 x 12 mm	5023925	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.5 x 12 mm	5023926	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.0 x 12 mm	5023927	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.5 x 12 mm	5023928	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124

<b>Device name</b> (under MDR application)	<b>Article number</b> (under MDR application)	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>Basic UDI-DI</b> (under MDR application)	<b>MDR Device classification</b> (as proposed by the manufacturer and verified during application review)	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
SeQuent NEO NC 2.0 x 15 mm	5023930	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.25 x 15 mm	5023931	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.5 x 15 mm	5023932	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.75 x 15 mm	5023933	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.0 x 15 mm	5023934	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.25 x 15 mm	5023935	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.5 x 15 mm	5023936	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.0 x 15 mm	5023937	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.5 x 15 mm	5023938	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.0 x 20 mm	5023940	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.25 x 20 mm	5023941	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.5 x 20 mm	5023942	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.75 x 20 mm	5023943	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.0 x 20 mm	5023944	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124

<b>Device name</b> (under MDR application)	<b>Article number</b> (under MDR application)	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>Basic UDI-DI</b> (under MDR application)	<b>MDR Device classification</b> (as proposed by the manufacturer and verified during application review)	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
SeQuent NEO NC 3.25 x 20 mm	5023945	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.5 x 20 mm	5023946	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.0 x 20 mm	5023947	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.5 x 20 mm	5023948	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.0 x 30 mm	5023960	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.25 x 30 mm	5023961	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.5 x 30 mm	5023962	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 2.75 x 30 mm	5023963	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.0 x 30 mm	5023964	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.25 x 30 mm	5023965	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 3.5 x 30 mm	5023966	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.0 x 30 mm	5023967	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124
SeQuent NEO NC 4.5 x 30 mm	5023968	N/A	40392390000013532A	Class III	51342-16-02_Rev 05; 51342-23-H0_Rev 00; both from NB #0124



**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:**

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	



### Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-07-09	713331199 / 713263785	Initial issue