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

B. Braun Melsungen AG
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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
12974	713329931_CL	medical_devices@tuvsud.com	N/A	2024-07-09	1 of 13

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 012974 0658 Rev. 00

Reference: 713329931_CL

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.

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 0658 Rev. 00

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

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

TÜV SÜD Product Service GmbH
[redacted]
Project Handler (PH)

TÜV SÜD Product Service GmbH
[redacted]
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**
Coroflex ISAR NEO 2.00 x 9 mm	5028910	N/A	4039239000013592N	Class III	☒ Certification as follows: Certificate #1 #51342-23-G1 Rev 02; NB#0124 Certificate #2;#51342-16-02 Rev 05 NB #0124
Coroflex ISAR NEO 2.25 x 9 mm	5028911				
Coroflex ISAR NEO 2.50 x 9 mm	5028912				
Coroflex ISAR NEO 2.75 x 9 mm	5028913				
Coroflex ISAR NEO 3.00 x 9 mm	5028914				
Coroflex ISAR NEO 3.50 x 9 mm	5028915				
Coroflex ISAR NEO 4.00 x 9 mm	5028916				
Coroflex ISAR NEO 2.00 x 12 mm	5028917				
Coroflex ISAR NEO 2.25 x 12 mm	5028918				

Coroflex ISAR NEO 2.50 x 12 mm	5028919				
Coroflex ISAR NEO 2.75 x 12 mm	5028920				
Coroflex ISAR NEO 3.00 x 12 mm	5028921				
Coroflex ISAR NEO 3.50 x 12 mm	5028922				
Coroflex ISAR NEO 4.00 x 12 mm	5028923				
Coroflex ISAR NEO 2.00 x 16 mm	5028924				
Coroflex ISAR NEO 2.25 x 16 mm	5028925				
Coroflex ISAR NEO 2.50 x 16 mm	5028926				
Coroflex ISAR NEO 2.75 x 16 mm	5028927				
Coroflex ISAR NEO 3.00 x 16 mm	5028928				
Coroflex ISAR NEO 3.50 x 16 mm	5028929				
Coroflex ISAR NEO 4.00 x 16 mm	5028930				

Coroflex ISAR NEO 2.00 x 19 mm	5028931				
Coroflex ISAR NEO 2.25 x 19 mm	5028932				
Coroflex ISAR NEO 2.50 x 19 mm	5028933				
Coroflex ISAR NEO 2.75 x 19 mm	5028934				
Coroflex ISAR NEO 3.00 x 19 mm	5028935				
Coroflex ISAR NEO 3.50 x 19 mm	5028936				
Coroflex ISAR NEO 4.00 x 19 mm	5028937				
Coroflex ISAR NEO 2.00 x 24 mm	5028938				
Coroflex ISAR NEO 2.25 x 24 mm	5028939				
Coroflex ISAR NEO 2.50 x 24 mm	5028940				
Coroflex ISAR NEO 2.75 x 24 mm	5028941				
Coroflex ISAR NEO 3.00 x 24 mm	5028942				

Coroflex ISAR NEO 3.50 x 24 mm	5028943				
Coroflex ISAR NEO 4.00 x 24 mm	5028944				
Coroflex ISAR NEO 2.00 x 28 mm	5028945				
Coroflex ISAR NEO 2.25 x 28 mm	5028946				
Coroflex ISAR NEO 2.50 x 28 mm	5028947				
Coroflex ISAR NEO 2.75 x 28 mm	5028948				
Coroflex ISAR NEO 3.00 x 28 mm	5028949				
Coroflex ISAR NEO 3.50 x 28 mm	5028950				
Coroflex ISAR NEO 4.00 x 28 mm	5028951				
Coroflex ISAR NEO 2.00 x 32 mm	5028952				
Coroflex ISAR NEO 2.25 x 32 mm	5028953				
Coroflex ISAR NEO 2.50 x 32 mm	5028954				

Coroflex ISAR NEO 2.75 x 32 mm	5028955				
Coroflex ISAR NEO 3.00 x 32 mm	5028956				
Coroflex ISAR NEO 3.50 x 32 mm	5028957				
Coroflex ISAR NEO 4.00 x 32 mm	5028958				
Coroflex ISAR NEO 2.00 x 38 mm	5028959				
Coroflex ISAR NEO 2.25 x 38 mm	5028960				
Coroflex ISAR NEO 2.50 x 38 mm	5028961				
Coroflex ISAR NEO 2.75 x 38 mm	5028962				
Coroflex ISAR NEO 3.00 x 38 mm	5028963				
Coroflex ISAR NEO 3.50 x 38 mm	5028964				
Coroflex ISAR NEO 4.00 x 38 mm	5028965				
Coroflex ISAR NEO 2.00 x 9 mm	5028910D				

Coroflex ISAR NEO 2.25 x 9 mm	5028911D				
Coroflex ISAR NEO 2.50 x 9 mm	5028912D				
Coroflex ISAR NEO 2.75 x 9 mm	5028913D				
Coroflex ISAR NEO 3.00 x 9 mm	5028914D				
Coroflex ISAR NEO 3.50 x 9 mm	5028915D				
Coroflex ISAR NEO 4.00 x 9 mm	5028916D				
Coroflex ISAR NEO 2.00 x 12 mm	5028917D				
Coroflex ISAR NEO 2.25 x 12 mm	5028918D				
Coroflex ISAR NEO 2.50 x 12 mm	5028919D				
Coroflex ISAR NEO 2.75 x 12 mm	5028920D				
Coroflex ISAR NEO 3.00 x 12 mm	5028921D				
Coroflex ISAR NEO 3.50 x 12 mm	5028922D				

Coroflex ISAR NEO 4.00 x 12 mm	5028923D				
Coroflex ISAR NEO 2.00 x 16 mm	5028924D				
Coroflex ISAR NEO 2.25 x 16 mm	5028925D				
Coroflex ISAR NEO 2.50 x 16 mm	5028926D				
Coroflex ISAR NEO 2.75 x 16 mm	5028927D				
Coroflex ISAR NEO 3.00 x 16 mm	5028928D				
Coroflex ISAR NEO 3.50 x 16 mm	5028929D				
Coroflex ISAR NEO 4.00 x 16 mm	5028930D				
Coroflex ISAR NEO 2.00 x 19 mm	5028931D				
Coroflex ISAR NEO 2.25 x 19 mm	5028932D				
Coroflex ISAR NEO 2.50 x 19 mm	5028933D				
Coroflex ISAR NEO 2.75 x 19 mm	5028934D				

Coroflex ISAR NEO 3.00 x 19 mm	5028935D				
Coroflex ISAR NEO 3.50 x 19 mm	5028936D				
Coroflex ISAR NEO 4.00 x 19 mm	5028937D				
Coroflex ISAR NEO 2.00 x 24 mm	5028938D				
Coroflex ISAR NEO 2.25 x 24 mm	5028939D				
Coroflex ISAR NEO 2.50 x 24 mm	5028940D				
Coroflex ISAR NEO 2.75 x 24 mm	5028941D				
Coroflex ISAR NEO 3.00 x 24 mm	5028942D				
Coroflex ISAR NEO 3.50 x 24 mm	5028943D				
Coroflex ISAR NEO 4.00 x 24 mm	5028944D				
Coroflex ISAR NEO 2.00 x 28 mm	5028945D				
Coroflex ISAR NEO 2.25 x 28 mm	5028946D				

Coroflex ISAR NEO 2.50 x 28 mm	5028947D				
Coroflex ISAR NEO 2.75 x 28 mm	5028948D				
Coroflex ISAR NEO 3.00 x 28 mm	5028949D				
Coroflex ISAR NEO 3.50 x 28 mm	5028950D				
Coroflex ISAR NEO 4.00 x 28 mm	5028951D				
Coroflex ISAR NEO 2.00 x 32 mm	5028952D				
Coroflex ISAR NEO 2.25 x 32 mm	5028953D				
Coroflex ISAR NEO 2.50 x 32 mm	5028954D				
Coroflex ISAR NEO 2.75 x 32 mm	5028955D				
Coroflex ISAR NEO 3.00 x 32 mm	5028956D				
Coroflex ISAR NEO 3.50 x 32 mm	5028957D				
Coroflex ISAR NEO 4.00 x 32 mm	5028958D				

Coroflex ISAR NEO 2.00 x 38 mm	5028959D				
Coroflex ISAR NEO 2.25 x 38 mm	5028960D				
Coroflex ISAR NEO 2.50 x 38 mm	5028961D				
Coroflex ISAR NEO 2.75 x 38 mm	5028962D				
Coroflex ISAR NEO 3.00 x 38 mm	5028963D				
Coroflex ISAR NEO 3.50 x 38 mm	5028964D				
Coroflex ISAR NEO 4.00 x 38 mm	5028965D				

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)	Device variants (if such exist)	Article number (under MDR application)	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

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-07-09	713329931	Initial issue