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

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

Your reference	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
12974	713337043 | 713333920	medical_devices@tuvsud.com.	n/a	2024-06-26	1 of 4

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 012974 0662 Rev. 00

Reference: **713337043 | 713333920**

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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 0662 Rev. 00

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

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

26th June 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 916405

Sabine Osterhues
Project Handler (PH)

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 798101

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**
Angiodyn Guide Wire J3150T35	5050200	n/a	40392390000015072D	Class III (under MDD class IIa)	G1 012974 0608 Rev 00 NB 0123
Angiodyn Guide Wire J3150T38	5050219				
Angiodyn Guide Wire J3F150T35	5050227				
Angiodyn Guide Wire J3M150T35	5050235				
Angiodyn Guide Wire S150T35	5050243				
Angiodyn G Wire J3150T32	5050260				
Angiodyn Guidewire J3 MC-FS 200-035	5050308				
Angiodyn Guide Wire J3260T35	5050359				
Angiodyn Guide Wire J3 SFC-FS 220-035	5050360				
Angiodyn G.Wire J3FC260-038	5050367				
Angiodyn G Wire S260T35	5050421				
Angiodyn G. Wire S260T38	5050430				
Angiodyn Guidewire SFC 150-018	5050456				
Angiodyn Guidewire J3 FC 150-025	5050511				
Guide Wire J3 FC-FS 200-035	5050980				
Guide Wire J3 FC-FS 220-035	5050981				
Angiodyn Guidewire J3 SFC-FS 150-038	5051022				
Angiodyn Guidewire J3FC-XX-FS 80-035	5053040				
Angiodyn Guidewire J3 MC-FS 150-032	5056470				
Angiodyn Guidewire J3 SFC-FS 175-035	5059208				
Guide Wire J3 FC-FS 175-035	5059755				

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	2024-06-06	713337043_CL	Initial issue