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

B. Braun Melsungen AG
Carl-Braun-Str. 1
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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
12974	713297097 | 713263785	medical_devices@tuvsud.com	n/a	2025-03-11	Page **1** of **11**

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 012974 0670 Rev. 02

Reference: 713297097 | 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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 0670 Rev. 02

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

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

11th March 2025.

TÜV SÜD Product Service GmbH
Medical and Health Services

Juergen Kunte (11. März 2025 15:20 GMT+1)

Jürgen Kunte
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Tunde Junaid
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 MDD & 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**
Inflation Device AI25	5028901*	5028902 | 5028905	403923900000136129	Class I devices in sterile condition (Class Is) | Class I devices with measuring function (Class Im)	G1 012974 0608 Rev 00 NB 0123
*Mentioned article code also applies to the article code under MDD					

Device name (under MDR application)	**Article Number** (under MDD & 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 Guidewire J3 SFU 70-035	5050472	n/a	40392390000015072D	Class IIa	G1 012974 0608 Rev 00 NB 0123
Intradyn Wire J3 SFU 45 - 035	5050529				
J-Guidewire 0.035"50 CM 50 cm w. Th. Push Disp	5053535				

Device name (under MDR application)	**Article Number** (under MDD & 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 Stopcock 84 bar, OFF	5012163*	5012155	40392390000015092H	Class IIa	G1 012974 0608 Rev 00 NB 0123
Angiodyn Stopcock 1200 psi OFF + Rot.	5015569	n/a			
Angiodyn Stopcock FRR 70 bar	5019506	n/a			
Stopcock for Blood Sampling	5200411	5200359 | 5213940			
3-Way-Stopcock red, large bore	5212871	n/a			
*Mentioned article code also applies to the article code under MDD					

Device name (under MDR application)	**Article Number** (under MDD & 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**
Manifold Softgrip 3-fold, OFF	5010575	n/a	40392390000015082F	Class IIa	G1 012974 0608 Rev 00 NB 0123
Manifold Softgrip 2-fold, OFF	5010576				
Manifold Softgrip 2-fold, ON	5010577				
Manifold Softgrip 3-fold, ON	5010579				
Manifold Softgrip MP 3-fold ON	5016131				
Manifold Softgrip MP 2-fold OFF	5011406				
Manifold Softgrip MP 2-fold ON	5011407				
Manifold Softgrip MP 3-fold OFF	5011404				
Angiodyn Manifold 3 FRR 35 bar	5012074				
Angiodyn Manifold 2 FRR 35 bar	5012112				
Angiodyn Manifold 2 ORR 35 bar	5012759				
Angiodyn Manifold 3 ORR 35 bar	5012813				

Device name (under MDR application)	**Article Number** (under MDD & 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 Rotating Adapter m /m, 70 bar	5018161	n/a	403923900000151022	Class IIa	G1 012974 0608 Rev 00 NB 0123
Angiodyn Rotating Adapter m/f, 70 bar	5018170				

Device name (under MDR application)	**Article Number** (under MDD & 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**
Angiographic Syringe 10 ml w male LL fitt	5010142*	5010120 | 5011990	403923900000151124	Class I devices in sterile condition (Class Is) | Class I devices with measuring function (Class Im)	G1 012974 0608 Rev 00 NB 0123
Disposable Syringe 10ml white LL	5018991	n/a			
Disposable Syringe 10ml red LL	5018992	n/a			
Disposable Syringe 10ml blue LL	5018993	n/a			
Disposable Syringe 10ml green LL	5018996	n/a			
Disposable Syringe 10ml yellow LL	5018997	n/a			
Disposable Syringe 20ml white LL	5018998*	5014866 | 5017469			
Disposable Syringe 20ml blue LL	5019004	n/a			
Disposable Syringe 20ml green LL	5019006	n/a			
Disposable Syringe 20ml yellow LL	5019013	n/a			
Disposable Syringe 20ml red LL	5019016	n/a			
*Mentioned article code also applies to the article code under MDD					

Device name (under MDR application)	**Article Number** (under MDD & 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**
Arteriofix 22G/80 mm	5206316	n/a	40392390000015142A	Class IIa	G1 012974 0608 Rev 00 NB 0123
Arteriofix 20G/80 mm	5206324				
Arteriofix 20G/160 mm	5206332				
Arteriofix 18G/160 mm	5206359				
Arteriofix 18G/80 mm	5206345				

Device name (under MDR application)	**Article Number** (under MDD & 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**
Arteriofix V Artery Cath. Kit 22G/80 mm	5206364	n/a	40392390000015152C	Class IIa	G1 012974 0608 Rev 00 NB 0123
Arteriofix V Artery Cath. Kit 20G/80 mm	5206363				
Arteriofix V Artery Cath. Kit 20G/160 mm	5206362				
Arteriofix V Artery Cath. Kit 18G/160 mm	5206361				

Device name (under MDR application)	**Article Number** (under MDD & 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**
Combidyn-press. Tube PE 240 cm, transp.	5201272	n/a	40392390000015192L	Class IIa	G1 012974 0608 Rev 00 NB 0123
Combidyn-press. Tube PE 120 cm, transp.	5201281				
Combidyn-press. Tube PE 180 cm, transp.	5201337				
Combidyn-press. Tube PE 60 cm, transp.	5201345				
Combidyn-press. Tube PE30 cm, red	5204950				
Combidyn-press. Tube PE30 cm, blue	5205239				
Combidyn press. Tube 150 cm blue m/m	5210577				
Combidyn-press. Tube PE 30 cm, transp.	5214993				
Combidyn-press. Tube PE 100 cm, transp.	5215019				
Combidyn-press. Tube PE 150 cm, transp.	5215027				
Combidyn-press. Tube PE 200 cm, transp	5215035				
Combidyn-press. Tube PE 150 cm, red	5215043				
Combidyn-press. Tube PE 150 cm blue	5215264				
Combidyn press. Tube w. 3-way stored 15	5218598				
Combidyn-press. Tube PE 15 cm, transp.	5204995				

Device name (under MDR application)	**Article Number** (under MDD & 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**
Combidyn PVC pressure tubing red 20 cm	5204941	n/a	40392390000152025	Class IIa	G1 012974 0608 Rev 00 NB 0123
Combidyn PVC pressure tubing red 100 cm	5204976				
Combidyn PVC press. tubing transp. 20 cm	5204984				
Combidyn PVC press. tubing transp. 30 cm	5204992				
Combidyn PVC press. tubing transp. 50 cm	5205000				
Combidyn PVC press. tubing transp. 100 cm	5205018				
Combidyn PVC press. tubing transp. 150 cm	5205026				
Combidyn PVC press. tubing transp. 200 cm	5205034				
Combidyn PVC pressure tubing red 150 cm	5205042				
Combidyn PVC press. tubing red 200 cm	5205050				
Combidyn PVC press. tubing blue 100 cm	5205255				
Combidyn pressure tubing blue 150 cm	5205263				
Combidyn pressure tubing blue 200 cm	5205271				
Combidyn press. Line 200 mm, transp.	5208000				
Combidyn press. line 1.5 x 2.7 x 300 mm transp	5208020				
Combidyn press. Line 750 mm, transp.	5208080				
Combidyn press. line 1000 mm, transp.	5208090				
Combidyn PVC tube with stopcock red 20 cm	5208599				
Combidyn PVC press. tubing transp. L125 cm	5211280				

Device name (under MDR application)	**Article Number** (under MDD & 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 Contrast-Saver Tube	5010552	n/a	40392390000015312A	Class IIa	G1 012974 0608 Rev 00 NB 0123
Angiodyn Contrast-Saver Spike	5010557*	5010551			
Contrast Saver Tubing 1800 mm	5010559	n/a			
Contrast Media Kit 150 cm	5019715	5014001			
*Mentioned article code also applies to the article code under MDD					

Device name (under MDR application)	**Article Number** (under MDD & 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**
Intradyn venous F6, J3-guide wire	5209749*	5210062	40392390000015392S	Class IIa	G1 012974 0608 Rev 00 NB 0123
Intradyn venous F7, J3-guide wire	5209757*	5210070			
Intradyn venous F8, J3-guide wire	5209765*	5210089			
Intradyn venous with valve F5	5210615	n/a			
*Mentioned article code also applies to the article code under MDD					

Device name (under MDR application)	**Article Number** (under MDD & 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**
Peelable Introducer 7cm 4 F	5010848*	5211870	403923900000015382Q	Class IIa	G1 012974 0608 Rev 00 NB 0123
Peelable Introducer 7cm 5 F	5010849	n/a			
Intradyn Tear-Away F6 with J3 Wire	5210313*	5010851 | 5211869			
Intradyn Tear-Away F7	5210593*	5214699			
Intradyn Tear-Away F8	5210321	n/a			
Intradyn Tear-Away F9	5210330*	5214698			
Intradyn Tear-Away F10 with J3 Wire	5210348*	5212537			
Intradyn Tear-Away F11	5210585*	5214297			
Tear Away Introducer 7cm 4.5 F	5014882	n/a			
Tear Away Introducer 7cm 5.5 F	5014883	n/a			
Tear Away Introducer 7cm 6.5 F	5014884	n/a			
*Mentioned article code also applies to the article code under MDD					

Device name (under MDR application)	**Article Number** (under MDD & 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**
Foilcover-Tube AG 2000 for Intradyn HVI	5210178	n/a	403923900000024912W	Class I devices in sterile condition (Class Is)	G1 012974 0608 Rev 00 NB 0123

Device name (under MDR application)	**Article Number** (under MDD & 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**
Seldinger Needle 0,80 x 50 mm G21	5013606	n/a	403923900000015402B	Class IIa	G1 012974 0608 Rev 00 NB 0123
Puncture-Needle Yellow 20G -0,95 x 70 mm	5013862				
Intradyn Introducer Needle	5208505				

Device name (under MDR application)	**Article Number** (under MDD & 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**
Intradyn Basic Set, F6	5010848*	5210950	4039239000002490 2U	Class IIa	G1 012974 0608 Rev 00 NB 0123
Intradyn Basic Set, F7	5010849	5210100			
Intradyn Basic Set, F8	5210313*	5210097			
Add-On Set fuer Eledyn 2/F6	5210593*	5150020			
Add-On Set fuer Eledyn 2/F5	5210321	5150021			

Device name (under MDR application)	**Article Number** (under MDD & 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**
Y-Connector – single sterile	5010434	n/a	40392390000020662B	Class IIa	G1 012974 0608 Rev 00 NB 0123
Y-Adapter 9.5F Lumen	5021596	n/a			
Y-Connector Single 9,5 F	5021693*	5028550			
Y-Connector 9,5 F double	5020743	n/a			
Y-Connector Flat Cap w. Insertion Tool	5022693*	5019602 | 5024103 | 5017826			
*Mentioned article code also applies to the article code under MDD					

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	2024/06/25	713297097 | 713263785	Initial issue
01	2025/02/18	713297097 | 713263785	Second Issue: issued due to correction of the Article number for the ´Foilcover Tube AG 2000 for Intradyn HVI' Device.
02	2025/03/11	713297097 | 713263785	Third Issue: Correction to add missing substitute device information to article 5200411 (Stopcock for Blood Sampling): Substitute for article numbers 5200359 | 5213940.