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

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GERMANY

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
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TÜV SÜD Product Service GmbH
Confirmation Letter
CL 012974 0663 Rev. 00

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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 0663 Rev. 00

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

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

20th June 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 916408
16.05.2024
Sabine Osterhues

Sabine Osterhues
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**
Angiodyn high press. tub. 84 bar 50 cm +rot.	5011507	n/a	403923900000151328	Class IIa	G1 012974 0608 Rev 00 NB 0123
Angiodyn high press. tube 84 bar 75 cm +rot	5011515				
Angiodyn high press. tube 84 bar 100 cm+rot.	5011523				
Angiodyn high press. tube 84 bar 120 cm+rot.	5011531				
Angiodyn high press. tube 70 bar 120 cm+rot.	5011938				
Angiodyn high press. tube 70 bar 50 cm +rot	5011957				
Angiodyn high press. tube 70 bar 75 cm +rot	5011965				
Angiodyn high press. tube 70 bar 100 cm +rot.	5011973				
Angiodyn high press. tube 70 bar 25 cm +rot	5014824				
Angiodyn high press. tube 70 bar 150 cm m/f	5014875				
Ang. high press. tube 200 cm,84 bar+ Rot	5016002				
Angiodyn high press. tube 70 bar 75 cm m/f	5018200				
Angiodyn high press. tube 70 bar 100 cm m/f	5018218				
Angiodyn high press. tube 70 bar 120 cm m/f	5018233				
Angiodyn high press. tube 150 cm, 70 bar	5018580				
Angiodyn HP-Tubing 25 cm 84 bar w. rot.ad.	5018864				
Angiodyn HP-Tubing 70bar 180cm + Rot.Ad.	5218088				
UKB Unique Kissing BiBallonadaptor	5014760*	5028904	40392390000015432H	Class IIa	G1 012974 0608 Rev 00 NB 0123
*Mentioned article code also applies to the article code under MDD.					

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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**
Combitrans 2-fold Monitoring-Kit	5200011	n/a	40392390000024812T	**Class IIb** / Class IIb implantable (exempted)	G1 012974 0608 Rev 00 NB 0123
Combitrans Monitoring Set double	5200830	n/a			
Combitrans Monitoring Set triple	5200849*	5318766 | 5318768 | 5319771			
Combitrans Monitoring Set 2-fold	5201152*	5201152-1 | 5318762 | 5318767 | 5318771 | 5319305			
Exadyn Combitrans Monitoring Kit	5202507*	5202507-0			
Combitrans Monitoring Set venous	5202604*	5202604-1 | 5312020 | 5313030 | 5319290			
Combitrans-Monitoring Set venous long	5202614	n/a			
Combitrans Monitoring Set pulmonary art.	5202617*	5318575			
Combitrans Arterial Monitoring Set	5202620*	5202620-1 | 5311010 | 5319289			
Combitrans transducer	5203660	n/a			
Exadyn Monitoring Set (long line)	5206994*	5318575			
Combitrans Monitoring Set Add-on	5207167*	5318776			
Combitrans Monitoring-Set	5211247	n/a			
Exadyn-Combitrans PVC-free	5212391	n/a			
Haemofix-Combitrans Kit 2- Fold BSS 4.8ml	5214040	5200181| 5213527			
Haemofix-Combitrans Kit 3-Fold BSS 4.8 ml	5215050	5200183 | 5311325 | 5213516 | 5319300			
Haemofix Combitrans Set arterial 4.8ml	5215454	5200182 | 5213505 | 5319295			
Combitrans Monitoring Set Velcro	5216200	n/a			
Angiotrans 2-Port, OFF Mid Pressure, RR	5019505	n/a	40392390000015232B	**Class IIb** / Class IIb implantable (exempted)	G1 012974 0608 Rev 00 NB 0123
*Mentioned article code also applies to the article code under MDD.					

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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	2024/06/20	713297097 | 713263785	Initial issue

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