TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
49319	713300557	+49 40 840521-117 Falko.doberenz@tuvsud.com		2023-11-20	1 of 13

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 049319 0010 Rev. 00

Reference: 713300557 | 713304151 | 713310887 | 713304152 | 713309539

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-000009201

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(MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further 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 049319 0010 Rev. 00

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2023-11-20

TÜV SÜD Product Service GmbH
Medical and Health Services

Falko Doberenz
Falko Doberenz (20. November 2023 15:41 GMT+1)

Falko Doberenz
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Mira Fischer
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 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
42503371DEFLSHA9V	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371DEFLRESAK	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371DEFLCUT9S	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371DEFLABR7K	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123

	☐ Class III implantable custom-made-device		
42503371ENSCARTFV	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371ENSCCSCF8	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371ENSCFORG9	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371ENSCLAMFK	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371ENSCMULHJ	☐ Class III ☐ Class IIb implantable ☐ Class IIb	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123

	☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
42503371ENSCNUCH5	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371ENSC4KFCG	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371REAMREAFD	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371REAMDRIEW	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123

	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
42503371ACNENEE7V	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371ACNENPP9L	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371VERSPUMSL	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371ACNENGW97	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371SHRI2CUJB	☐ Class III	☒ N/A	☒ Certification as follows:

	☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		G1 049319 0002 Rev.00; 0123
42503371SHRI2HPJG	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371ENDO2AK	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371EPROPROLZ	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371PEPLSCMKY	☐ Class III ☒ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123

	☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
42503371PEPLSCRLA	☐ Class III ☒ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123
42503371PEPLSTALT	☐ Class III ☒ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 049319 0002 Rev.00; 0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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**
42503371SHRIDEFLU7	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371PALPENDG5	☐ Class III ☐ Class IIb implantable ☐ Class IIb	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

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
	☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
42503371GUWIGUWPV	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INCATRIEC	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INCAINSCV	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INCAPUSEM	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

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
	☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
42503371INSRRHONP	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INSRBRELH	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INSRINSN4	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INSRDRIM3	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

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
	☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
42503371INSRTULQ2	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INSRTUBPE	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INSRREVNU	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INSRRODNN	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

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
	☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
42503371AWLAWLD6	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371N+VI2SW84	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371EPROVFSM3	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INNATROJH	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

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
	☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
42503371N+VI28G	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I reusable surgical instruments ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2023-11-20	713300557	Intial Issue