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TÜV SÜD Product Service GmbH · Sylvesterallee 2 · 22525 Hamburg · Germany

joimax® GmbH
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Amalienbadstraße 41
76227 Karlsruhe

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
CN joimax_MDR_Class Ila_2024-09-24	713348793	/	/	2024-12-03	1 of 8

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 049319 0010 Rev. 01**

Reference: 713300557 | 713304151 | 713310887 | 713304152 | 713309539 | 713348793

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.

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Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 049319 0010 Rev. 01

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-12-03

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to read "A. Bojak".

SIGN-ID 985509
03.12.2024

Alexandra Bojak
Dr. Alexandra Bojak
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Arianit Fazlija-Diem
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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371DEFLRESAK	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371DEFLCUT9S	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371DEFLABR7K	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371ENSCARTFV	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371ENSCCSCF8	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371ENSCFOR9	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371ENSCLAMFK	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371ENSCMULHJ	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371ENSCNUCH5	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371ENSC4KFCG	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows:



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
			Certificate G1 049319 0002 Rev.00 NB 0123
42503371REAMREAFD	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371REAMDRIEW	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371ACNENE7V	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371ACNENPP9L	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371VERSPUMSL	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371ACNENGW97	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371SHRI2CUJB	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371SHRI2HPJG	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371TUBESETNV	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371TEACSETFL	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371TEACSET1M7	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123



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
42503371ENDO2AK	<input checked="" type="checkbox"/> Class IIb	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371EPROPROLZ	<input checked="" type="checkbox"/> Class IIb	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371PEPLSCMKY	<input checked="" type="checkbox"/> Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371PEPLSCRLA	<input checked="" type="checkbox"/> Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123
42503371PEPLSTALT	<input checked="" type="checkbox"/> Class IIb implantable (exempted)	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> Certification as follows: Certificate G1 049319 0002 Rev.00 NB 0123



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 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	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371PALPENDG5	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371GUWIGUWPV	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INCATRIEC	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INCAINSCV	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INCAPUSEM	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INSRRHONP	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INSRBRELH	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INSRINSN4	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INSRDRIM3	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INSRTULQ2	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INSRTUBPE	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INSRREVNU	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INSRRODNN	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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
42503371AWLAWLD6	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371N+VI2SW84	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371EPROVFSM3	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371INNATROJH	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371N+VI28G	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371ENSCOBTGK	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
42503371ENSCLAMFK	<input checked="" type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 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	Initial issue.
2024/12/03	713348793	Amendment of the Confirmation Letter CL 049319 0010 Rev 00 to include additional class IIa legacy devices. New BUDIs added to Table 1: 42503371TUBESETNV, 42503371TEACSETFL, 42503371TEACSET1M7. New BUDIs added to Table 2: 42503371ENSCOBTGK, 42503371ENSCLAMFK.