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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
49319	713300496	+49 40 840521-117 falko.doberenz@tuvsud.com		2023-11-17	1 of 10

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 049319 0009 Rev. 00

Reference: 713300496 | 2057918 | 5817576

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 0009 Rev. 00

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2023-11-17

TÜV SÜD Product Service GmbH
Medical and Health Services

Falko Doberenz
Falko Doberenz (20. November 2023 08:29 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
☒ **N/A**	☒ N/A	☒ N/A	☒ N/A

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
42503371ABLACHI4Q	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371ABLACUR6H	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371ABLADIS5L	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments	☒ 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 III implantable custom-made-device		
42503371AWLAWLD6	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371AWLPERE7	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371AWLSTYGH	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371DILADIL9L	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments	☒ 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 III implantable custom-made-device		
42503371FORCCROGG	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371FORCFORGU	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371FORCGRAG8	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371FORCPUNJQ	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments	☒ 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 III implantable custom-made-device		
42503371FORCSEMHM	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371FORCSHIHN	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INCARASD3	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INCASPREK	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments	☒ 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 III implantable custom-made-device		
42503371INSROPENC	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371INSRRULPQ	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371PALPELEFZ	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ 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 ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments	☒ 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 III implantable custom-made-device		
42503371PALPEXAGV	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371PALPHOOHD	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371PUNCHENDWR	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371REAMDILE9	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments	☒ 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 III implantable custom-made-device		
42503371REAMDRIEW	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371REAMREAFD	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371WOTULUCX3	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371WOTUSCPXA	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments	☒ 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 III implantable custom-made-device		
42503371WOTUSCSXG	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
42503371WOTUTUBY9	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☒ Class I reusable surgical instruments ☐ 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
17/11/2023	713300496	Initial issue