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

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6340 BAAR
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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
11634	713181494 | 713221267 | 713316123	medical_devices@tuvsud.com	N/A	2024-05-06	1 of 12

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 011634 0247 Rev. 00

Reference: 713181494 | 713221267 | 713316123

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: CH-MF-000018913

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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 www.tuvsud.com/ps-cert?q=CL 011634 0247 Rev. 00

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

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

2024.05.06

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 913052
06.05.2024
Nico Bartholome
Bartholome Nico
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 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
Basic UDI-DI: 07612367gowgvnPR Disposable tubes Sterile	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2S 011634 0169 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367iljjakJZ Invia Transparent Film Sterile	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2S 011634 0169 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367jrnhbmN9 Disposable fingertip tubing Sterile	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2S 011634 0169 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367qsqsovVL Invia Motion Canister Sterile	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G2S 011634 0169 Rev. 02 NB 0123: Tüv Süd Product Service

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 devices with measuring function ☐ Class III implantable custom-made-device		
Basic UDI-DI: 07612367yucdoqTT Invia Liberty Canister / Tubing Sterile	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2S 011634 0169 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367zdiwyuTU Invia Drain Adapter / Invia Y-Connector with Quick Connector	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2S 011634 0169 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367ztdtbfUP Thopaz Canisters / Tubings / Caps Sterile	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G2S 011634 0169 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367ammmqiJL Vario kits	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service

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 devices with measuring function ☐ Class III implantable custom-made-device		
Basic UDI-DI: 07612367ancwxhJW Invia Gauze Dressing Kit with FitPad Sterile	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367dplhgdJL Basic	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367jlgntuMS IKRK Set Basic	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367jnkvtcPG Thopaz + / Thopaz	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02

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 IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367jwklgjQ8 Invia Abdominal Dressing Kit Sterile	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367jxoldhR2 Clario / Clario Toni	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367ksekhwNP Reusable Vacuum Assisted Delivery Cup	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367ksoirdQB	☐ Class III	☒ N/A	☒ Certification as follows: Certificate:

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
Invia Motion Negative Pressure Wound Therapy	☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367mgsgptND Single Use Vacuum Assisted Delivery Cup sterile	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367nhukziQF Invia Foam Dressing Kit with FitPad Sterile	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367ojntxmRG Dominant Flex	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service

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
Basic UDI-DI: 07612367ritufySV Invia Liberty Negative Pressure Wound Therapy	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367trhtdpT9 PersonalFit PLUS Breast shield	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367tovtfiV2 Hydrogel Pads	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367vbwoafQ6 Manual Vacuum Extractor Kits	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service

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		
Basic UDI-DI: 07612367zxvkpfZW Vario	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367dtbtnyMM Ready-to-Use Single-Use Bottle	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367gzhvgcQH Ready-to-Use One-Day Symphony Pump Set	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367kvskvsTU Sterile Single-Use Symphony Pump Set	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service

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 with measuring function ☐ Class III implantable custom-made-device		
Basic UDI-DI: 07612367lzqdsvTZ Symphony Pump set with PersonalFit PLUS - Ready-to-Use	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367qzzaegVA Sterile Single-Use Bottle	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367qizsugTR Symphony Pump set with PersonalFit PLUS - Sterile	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service
Basic UDI-DI: 07612367rrsgpsU5 Symphony Pump Set Excluding articles: 101043750; 101043751; 101043752; 101043753	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service

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 devices with measuring function ☐ Class III implantable custom-made-device		
Basic UDI-DI: 07612367derqtnKD Membrane for PersonalFit PLUS / Tubing for PersonalFit PLUS/ Symphony Cap for PersonalFit PLUS/ Symphony Connector Kit	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate: G1 011634 0195 Rev. 02 NB 0123: Tüv Süd Product Service

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 Revision History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/05/06	713181494 | 713221267 | 713316123	Initial issue