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

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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
22777	713318598	marina.stempfle@tuvsud.com Stempfle Marina	+49 89 50084-621	2024-02-14	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 022777 0031 Rev. 00

Reference: 713318598

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-000012295

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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=CL 022777 0031 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
14th February 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

Marina Stempfle
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

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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
4038953-AS-24-30-VD (SYMPATICO quiX 6 G6,SYMPATICO quiX 4 G6,IF 10 quick 6.6,IF 10 quick 6.4,OZ 20 ITE G6,OZ 40 ITE G6,IF 10 quick 6.8,IF 10 quick 6.16,quiX 4 G6,quiX 6 G6,CROS quiX G6,tune quiX G6,tune T2.0 quiX G6,quiX 8 G6,quiX 12 G6,quiX 16 G6)	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4038953-AS-25-15-VV (OZ TINI,inSync R S8,inSync R S6,inSync R S4,inSync R S2,inSync R S1,SYMPATICO Mood Li 4 G6,SYMPATICO Mood Li 6 G6,SYMPATICO Mood Li 8 G6,SYMPATICO Mood Li 16 G6,RIC Li Spirit 6.4,RIC Li Spirit 6.6,IC 8 RIC Li G6,IC 16 RIC Li G6,OZ 20 RIC Li G6,OZ 40 RIC Li G6,Demo CROS RIC Li-Ion G6,RIC Li Spirit 6.16,RIC Li Spirit 6.12,RIC Li Spirit 6.8,Mood Li-Ion 4 G6,Mood Li-Ion 6 G6,tune Mood Li-Ion G6,tune T2.0 Mood Li-Ion G6,Mood Li-Ion 8 G6,Mood Li-Ion 12 G6,Mood Li-Ion 16 G6,CROS RIC Li-Ion G6)	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4038953-AS-25-17-W3 (OZ 20 Slim G6,OZ 40 Slim G6,Stiline 6 G6,Stiline 4 G6,tune Stiline G6,tune T2.0 Stiline	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or

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**
G6,Stiline 8 G6,Stiline 12 G6,Stiline 16 G6)	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4038953-AS-24-15-VJ (inSync S2,inSync S1,SYMPATICO Mood 6 G6,SYMPATICO Mood 16 G6,IC 8 RIC 312 G6,IC 16 RIC 312 G6,OZ 20 RIC 312 G6,OZ 40 RIC 312 G6,SYMPATICO Mood 8 G6,Demo CROS RIC G6,inSync S4,inSync S6,inSync S8,RIC 312 Spirit 6.16,RIC 312 Spirit 6.12,RIC 312 Spirit 6.8,Mood 6 G6,Mood 4 G6,CROS RIC G6,tune Mood G6,tune T2.0 Mood G6,Mood 8 G6,Mood 12 G6,Mood 16 G6)	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4038953-AS-23-15-V7 (CROS RIC LI-ION G5)	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4038953-AS-20-10-TP (ECO 2 BASIC XS,OZ BTE 13 15 G4,ECO 2 BASIC,SYMPATICO XS 3 G4,SYMPATICO DUO 3 G4,OZ TDEMO BTE 13 G4,TUNE T 2.0 HP G4,TUNE T 2.0 P G4,DUO 3 G4,DUO 4 G4,DUO 6 G4,P 6 G4,P 4	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)

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
G4,TUNE DUO G4 A,TUNE T 2.0 XS G4,TUNE XS G4,VOLTA XS M,XS 8 G4,TUNE P G4 A,TUNE T HP G4,TUNE T 2.0 DUO G4 A,HP 3 G4,TUNE T P G4 A,HP 4 G4,P 3 G4,XS 3 G4,XS 4 G4,XS 6 G4,HP 6 G4,VOLTA HP T,HP 8 G4,HP 12 G4,HP 16 G4,TUNE T 2.0 P G4,P 8 G4,P 12 G4,P 16 G4,VOLTA HP M,VOLTA HP C,VOLTA P B,VOLTA P T,VOLTA P M,VOLTA P C,VOLTA XS C,TUNE HP G4,TUNE P G4)	☐ Class III implantable custom-made-device		Evidence #1; CA# Evidence #2; CA#
4038953-AS-20-15-U6 (SYMPATICO Mood 3 G4,ECO 2 BASIC PLUS,OZ RIC 312 15 G4,MOOD 3 G4,IC 6 G4 RIC 312,OZ RIC 312 20 G4,TUNE T 2.0 MOOD G4,MOOD 4 G4,MOOD 6 G4,TUNE T MOOD G4,MOOD 8 G4,MOOD 12 G4,MOOD 16 G4,TUNE MOOD G4)	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4038953-AS-21-25-UN (Icon 8 G5,Icon 12 G5,Icon 16 G5,Icon 4 G5 Precise,Icon 8 G5 Precise,Icon 6 G5 Precise,Icon 4 G5,Icon 6 G5,Ida BT 4 G5,Ida BT 6 G5,Ilea 6 G5,Ilea 4 G5,Icon 16 G5 Precise,Icon 12 G5 Precise,SINA 16 G5,SINA 12 G5,INSIDE SINA 8 G5,INSIDE IDA BT 8 G5,INSIDE IDA BT 12 G5,INSIDE IDA BT 16 G5,TUNE IDA BT G5,Ilea	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

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
16 G5,INSIDE SINA 16 G5,Ilea 12 G5,INSIDE SINA 12 G5,Ilea 8 G5,SINA 8 G5,Ida BT 16 G5,Icon 16 G5,Ida BT 12 G5,Icon 12 G5,Ida BT 8 G5,Icon 8 G5)			
4038953-AS-20-30-TZ (VOLTA QUIX P C, VOLTA QUIX C,OZ ITE 20 G4,OZ ITE 40 G4,QUIX P 3 G4,VOLTA QUIX M,VOLTA QUIX P M,QUIX 3 G4)	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4038953-AS-20-25-UB (Sina 8 G4,Icon 8 G4 Mini CIC,Ida 8 G4,Vega 8 G4,Sina 12 G4,Vega 16 G4,Icon 12 G4 Mini CIC,Ida 12 G4,Vega 12 G4,Ilea 3 G4,Icon 3 G4,ITE 3 G4,ITE 4 G4,ITE 6 G4,ITE 16 G4)	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4038953-AS-20-20-TU (VEGA VOLTA C,HYPE 3 G4,HYPE 4 G4,HYPE 6 G4,SINA VOLTA C)	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4038953-AS-21-15-UH (CROS RIC G5, MOOD 8 G5)	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A or	☒ Certification as follows: G1 022777 0030 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
	☒ 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	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
4038953-AS-21-30-UC (QUIX 8 G5)	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 022777 0030 Rev. 00; NB 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

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: 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
2024/02/14	**713318598**	Initial issue