



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 041151 0014 Rev. 00

Manufacturer:

AT-OS S.r.l.

Viale del Lavoro 19
37030 Colognola ai Colli (VR)
ITALY

Facility(ies):

AT-OS S.r.l.
Viale del Lavoro 19, 37030 Colognola ai Colli (VR), ITALY

**Product Category(ies): Washer-disinfectors for
non active medical devices**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

ITA1339913

Valid from:

2019-08-27

Valid until:

2024-05-26

Date,

2019-08-27

Stefan Preiß

Head of Certification/Notified Body



**Add value.
Inspire trust.**

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

AT-OS S.r.l.
Viale del Lavoro 19
37030 COGNOLA AI COLLI (VR)
ITALY

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
041151	713294212; ITA1992645_CL; ITA200220003828_CL; ITA200220006001; 713349046	+39 3489010334 Paolo.Bolelli@tuvsud.com	-	2024-10-07	1 of 25

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 041151 0015 Rev. 02**

Reference: 713294212 | ITA1992645_CL | ITA200220003828_CL | ITA200220006001 | 713349046

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: **IT-MF-000028623**

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.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Certification Body for Medical Products
Ridlerstr. 65
80339 Munich
Germany

tuvsud.com/ps
Hotline: +49 89 50084-747





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=CL_041151_0015

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-10-07

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services

Paolo Bolelli
[Paolo Bolelli \(Oct 7, 2024 13:58 GMT+2\)](#)

Paolo Bolelli
Conformity Assessment Responsible (CARE)

Michael Mauermeir
[Michael Mauermeir \(Oct 7, 2024 12:58 GMT+2\)](#)

Michael Mauermeir
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
AF2.45MEG-P17 AF2.45MEG-P21 AF2.45MEG-P23 AF2.45MEG-P19 AF2.45MEG-P11 AF2.45MEG-P06 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.45MEG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.45MEV-P17 AF2.45MEV-P21 AF2.45MEV-P23 AF2.45MEV-P19 AF2.45MEV-P11 AF2.45MEV-P06 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.45MEV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.45MG-P17 AF2.45MG-P21 AF2.45MG-P23 AF2.45MG-P19 AF2.45MG-P11 AF2.45MG-P06 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.45MG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.45MV-P17 AF2.45MV-P21 AF2.45MV-P23 AF2.45MV-P19 AF2.45MV-P11 AF2.45MV-P06 BASIC UDI-DI:	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 041151 0014 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
805673649AF2LK	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	AF2.45MV	
AF2.45PEG-P17 AF2.45PEG-P21 AF2.45PEG-P23 AF2.45PEG-P19 AF2.45PEG-P11 AF2.45PEG-P06 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.45PEG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.45PEV-P17 AF2.45PEV-P21 AF2.45PEV-P23 AF2.45PEV-P19 AF2.45PEV-P11 AF2.45PEV-P06 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.45PEV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.45PG-P17 AF2.45PG-P21 AF2.45PG-P23 AF2.45PG-P19 AF2.45PG-P11 AF2.45PG-P06 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.45PG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.45PV-P17 AF2.45PV-P21 AF2.45PV-P23 AF2.45PV-P19 AF2.45PV-P11 AF2.45PV-P06	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: G1 041151 0014 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
BASIC UDI-DI: 805673649AF2LK	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number: AF2.45PV	
AF2.60MEG-P17 AF2.60MEG-P21 AF2.60MEG-P23 AF2.60MEG-P19 AF2.60MEG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.60MEG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60METG-P17 AF2.60METG-P21 AF2.60METG-P23 AF2.60METG-P19 AF2.60METG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.60METG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60METV-P17 AF2.60METV-P21 AF2.60METV-P23 AF2.60METV-P19 AF2.60METV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.60METV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60MEV-P17 AF2.60MEV-P21 AF2.60MEV-P23 AF2.60MEV-P19 AF2.60MEV-P11	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☐ N/A or	☒ Certification as follows: G1 041151 0014 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
BASIC UDI-DI: 805673649AF2LK	☒ 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: AF2.60MEV	
AF2.60MG-P17 AF2.60MG-P21 AF2.60MG-P23 AF2.60MG-P19 AF2.60MG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.60MG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60MV-P17 AF2.60MV-P21 AF2.60MV-P23 AF2.60MV-P19 AF2.60MV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.60MV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60PEG-P17 AF2.60PEG-P21 AF2.60PEG-P23 AF2.60PEG-P19 AF2.60PEG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.60PEG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60PETG-P17 AF2.60PETG-P21 AF2.60PETG-P23 AF2.60PETG-P19	☐ Class III ☐ Class IIb implantable (non-exempted)	☐ N/A or	☒ Certification as follows: G1 041151 0014 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
AF2.60PETG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.60PETG	
AF2.60PETV-P17 AF2.60PETV-P21 AF2.60PETV-P23 AF2.60PETV-P19 AF2.60PETV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.60PETV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60PEV-P17 AF2.60PEV-P21 AF2.60PEV-P23 AF2.60PEV-P19 AF2.60PEV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.60PEV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60PG-P17 AF2.60PG-P21 AF2.60PG-P23 AF2.60PG-P19 AF2.60PG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.60PG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60PV-P17 AF2.60PV-P21	☐ Class III	☐ N/A	☒ Certification as follows: G1 041151 0014 Rev. 00;



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
AF2.60PV-P23 AF2.60PV-P19 AF2.60PV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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	or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: AF2.60PV	NB# 0123
AF2.60XMEG-P17 AF2.60XMEG-P21 AF2.60XMEG-P23 AF2.60XMEG-P19 AF2.60XMEG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X60MEG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60XMEV-P17 AF2.60XMEV-P21 AF2.60XMEV-P23 AF2.60XMEV-P19 AF2.60XMEV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X60MEV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60XMEV-P17 AF2.60XMEV-P21 AF2.60XMEV-P23 AF2.60XMEV-P19 AF2.60XMEV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X60MEV	☒ Certification as follows: G1 041151 0014 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
AF2.60XMG-P17 AF2.60XMG-P21 AF2.60XMG-P23 AF2.60XMG-P19 AF2.60XMG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X60MG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60XMV-P17 AF2.60XMV-P21 AF2.60XMV-P23 AF2.60XMV-P19 AF2.60XMV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X60MV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60XPEG-P17 AF2.60XPEG-P21 AF2.60XPEG-P23 AF2.60XPEG-P19 AF2.60XPEG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X60PEG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60XPEV-P17 AF2.60XPEV-P21 AF2.60XPEV-P23 AF2.60XPEV-P19 AF2.60XPEV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X60PEV	☒ Certification as follows: G1 041151 0014 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 III implantable custom-made-device		
AF2.60XPG-P17 AF2.60XPG-P21 AF2.60XPG-P23 AF2.60XPG-P19 AF2.60XPG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X60PG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.60XPV-P17 AF2.60XPV-P21 AF2.60XPV-P23 AF2.60XPV-P19 AF2.60XPV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X60PV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90AG-P17 AF2.90AG-P21 AF2.90AG-P23 AF2.90AG-P19 AF2.90AG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.90AG/860	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90ATG-P17 AF2.90ATG-P21 AF2.90ATG-P23 AF2.90ATG-P19 AF2.90ATG-P11 BASIC UDI-DI: 805673649AF2LK	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: AF2.90ATG/860	☒ Certification as follows: G1 041151 0014 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 I devices with measuring function ☐ Class III implantable custom-made-device		
AF2.90ATV-P17 AF2.90ATV-P21 AF2.90ATV-P23 AF2.90ATV-P19 AF2.90ATV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.90ATV/860	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90AV-P17 AF2.90AV-P21 AF2.90AV-P23 AF2.90AV-P19 AF2.90AV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.90AV/860	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90BAG-P17 AF2.90BAG-P21 AF2.90BAG-P23 AF2.90BAG-P19 AF2.90BAG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.90BAG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90BATG-P17 AF2.90BATG-P21 AF2.90BATG-P23 AF2.90BATG-P19 AF2.90BATG-P11 BASIC UDI-DI:	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: G1 041151 0014 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
805673649AF2LK	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number: AF2.90BATG	
AF2.90BATV-P17 AF2.90BATV-P21 AF2.90BATV-P23 AF2.90BATV-P19 AF2.90BATV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.90BATV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90BAV-P17 AF2.90BAV-P21 AF2.90BAV-P23 AF2.90BAV-P19 AF2.90BAV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.90BAV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90BG-P17 AF2.90BG-P21 AF2.90BG-P23 AF2.90BG-P19 AF2.90BG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.90BG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90BV-P17 AF2.90BV-P21 AF2.90BV-P23 AF2.90BV-P19 AF2.90BV-P11	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☐ N/A or	☒ Certification as follows: G1 041151 0014 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
BASIC UDI-DI: 805673649AF2LK	☒ 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: AF2.90BV	
AF2.90G-P17 AF2.90G-P21 AF2.90G-P23 AF2.90G-P19 AF2.90G-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.90G/860	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90V-P17 AF2.90V-P21 AF2.90V-P23 AF2.90V-P19 AF2.90V-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.90V/860	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90XBAG-P17 AF2.90XBAG-P21 AF2.90XBAG-P23 AF2.90XBAG-P19 AF2.90XBAG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X90BAG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90XBAG-P17 AF2.90XBAG-P21 AF2.90XBAG-P23 AF2.90XBAG-P19	☐ Class III ☐ Class IIb implantable (non-exempted)	☐ N/A or	☒ Certification as follows: G1 041151 0014 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
AF2.90XBAG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X90BAG	
AF2.90XBAV-P17 AF2.90XBAV-P21 AF2.90XBAV-P23 AF2.90XBAV-P19 AF2.90XBAV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X90BAV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90XBG-P17 AF2.90XBG-P21 AF2.90XBG-P23 AF2.90XBG-P19 AF2.90XBG-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X90BG	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.90XBV-P17 AF2.90XBV-P21 AF2.90XBV-P23 AF2.90XBV-P19 AF2.90XBV-P11 BASIC UDI-DI: 805673649AF2LK	☐ 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: AF2.X90BV	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AWD655-2-P11 AWD655-2-P10	☐ Class III	☐ N/A	☒ Certification as follows: G1 041151 0014 Rev. 00;



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
AWD655-2X-P11 AWD655-2X-P10 AWD655-2E-P11 AWD655-2E-P10 AWD655-2XE-P11 AWD655-2XE-P10 BASIC UDI-DI: 805673649AWD655FC	☐ 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	or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: AWD655-2	NB# 0123
AWD655-2H-P11 AWD655-2H-P10 AWD655-2HX-P11 AWD655-2HX-P10 AWD655-2HE-P11 AWD655-2HE-P10 AWD655-2HXE-P11 AWD655-2HXE-P10 BASIC UDI-DI: 805673649AWD655FC	☐ 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: AWD655-2H	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AWD655-8-P01 AWD655-8-P02 AWD655-8-P03 AWD655-8-P04 AWD655-8-P05 AWD655-8-P06 AWD655-8-P07 AWD655-8-P08 AWD655-8-P09 AWD655-8XE-P01 AWD655-8XE-P02 AWD655-8XE-P03 AWD655-8XE-P04 AWD655-8XE-P05 AWD655-8XE-P06 AWD655-8XE-P07 AWD655-8XE-P08 AWD655-8XE-P09 AWD655-8E-P01 AWD655-8E-P02 AWD655-8E-P03 AWD655-8E-P04 AWD655-8E-P05 AWD655-8E-P06	☐ 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: AWD655-8	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classifica- tion (as proposed by the manufacturer and verified during appli- cation review)	If the MDR device is a sub- stitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
AWD655-8E-P07 AWD655-8E-P08 AWD655-8E-P09 AWD655-8X-P01 AWD655-8X-P02 AWD655-8X-P03 AWD655-8X-P04 AWD655-8X-P05 AWD655-8X-P06 AWD655-8X-P07 AWD655-8X-P08 AWD655-8X-P09 BASIC UDI-DI: 805673649AWD655FC			
AWD655-8L-P01 AWD655-8L-P02 AWD655-8L-P03 AWD655-8L-P04 AWD655-8L-P05 AWD655-8L-P06 AWD655-8L-P07 AWD655-8L-P08 AWD655-8L-P09 AWD655-8XEL-P01 AWD655-8XEL-P02 AWD655-8XEL-P03 AWD655-8XEL-P04 AWD655-8XEL-P05 AWD655-8XEL-P06 AWD655-8XEL-P07 AWD655-8XEL-P08 AWD655-8XEL-P09 AWD655-8EL-P01 AWD655-8EL-P02 AWD655-8EL-P03 AWD655-8EL-P04 AWD655-8EL-P05 AWD655-8EL-P06 AWD655-8EL-P07 AWD655-8EL-P08 AWD655-8EL-P09 AWD655-8XL-P01 AWD655-8XL-P02 AWD655-8XL-P03 AWD655-8XL-P04	☐ 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 corre- sponding device under MDD/AIMDD Individual Article number: AWD655-8L	☒ Certification as follows: G1 041151 0014 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
AWD655-8XL-P05 AWD655-8XL-P06 AWD655-8XL-P07 AWD655-8XL-P08 AWD655-8XL-P09 BASIC UDI-DI: 805673649AWD655FC			
AWD655-8L-SC-P01 AWD655-8L-SC-P02 AWD655-8L-SC-P03 AWD655-8L-SC-P04 AWD655-8L-SC-P05 AWD655-8L-SC-P06 AWD655-8L-SC-P07 AWD655-8L-SC-P08 AWD655-8L-SC-P09 AWD655-8EL-SC-P01 AWD655-8EL-SC-P02 AWD655-8EL-SC-P03 AWD655-8EL-SC-P04 AWD655-8EL-SC-P05 AWD655-8EL-SC-P06 AWD655-8EL-SC-P07 AWD655-8EL-SC-P08 AWD655-8EL-SC-P09 AWD655-8XL-SC-P01 AWD655-8XL-SC-P02 AWD655-8XL-SC-P03 AWD655-8XL-SC-P04 AWD655-8XL-SC-P05 AWD655-8XL-SC-P06 AWD655-8XL-SC-P07 AWD655-8XL-SC-P08 AWD655-8XL-SC-P09 AWD655-8XEL-SC-P01 AWD655-8XEL-SC-P02 AWD655-8XEL-SC-P03 AWD655-8XEL-SC-P04 AWD655-8XEL-SC-P05 AWD655-8XEL-SC-P06 AWD655-8XEL-SC-P07 AWD655-8XEL-SC-P08 AWD655-8XEL-SC-P09 BASIC UDI-DI:	☐ 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: AWD655-8L-SC	☒ Certification as follows: G1 041151 0014 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
805673649AWD655FC			
AWD655-10-P01 AWD655-10-P02 AWD655-10-P14 AWD655-10-P15 AWD655-10-P16 AWD655-10X-P01 AWD655-10X-P02 AWD655-10X-P14 AWD655-10X-P15 AWD655-10X-P16 AWD655-10E-P01 AWD655-10E-P02 AWD655-10E-P14 AWD655-10E-P15 AWD655-10E-P16 AWD655-10XE-P01 AWD655-10XE-P02 AWD655-10XE-P14 AWD655-10XE-P15 AWD655-10XE-P16 BASIC UDI-DI: 805673649AWD655FC	☐ 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: AWD655-10	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AWD655-10-SC-P01 AWD655-10-SC-P02 AWD655-10-SC-P14 AWD655-10-SC-P15 AWD655-10-SC-P16 AWD655-10X-SC-P01 AWD655-10X-SC-P02 AWD655-10X-SC-P14 AWD655-10X-SC-P15 AWD655-10X-SC-P16 AWD655-10E-SC-P01 AWD655-10E-SC-P02 AWD655-10E-SC-P14 AWD655-10E-SC-P15 AWD655-10E-SC-P16 AWD655-10XE-SC-P01 AWD655-10XE-SC-P02 AWD655-10XE-SC-P14 AWD655-10XE-SC-P15 AWD655-10XE-SC-P16 BASIC UDI-DI:	☐ 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: AWD655-10-SC	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classifica- tion (as proposed by the manufacturer and verified during appli- cation review)	If the MDR device is a sub- stitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
805673649AWD655FC			
AWD655-10A-P01 AWD655-10A-P02 AWD655-10A-P14 AWD655-10A-P15 AWD655-10A-P16 AWD655-10AE-P01 AWD655-10AE-P02 AWD655-10AE-P14 AWD655-10AE-P15 AWD655-10AE-P16 BASIC UDI-DI: 805673649AWD655FC	☐ 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 corre- sponding device under MDD/AIMDD Individual Article number: AWD655-10A	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AWD655-10A-SC-P01 AWD655-10A-SC-P02 AWD655-10A-SC-P14 AWD655-10A-SC-P15 AWD655-10A-SC-P16 AWD655-10AE-SC-P01 AWD655-10AE-SC-P02 AWD655-10AE-SC-P14 AWD655-10AE-SC-P15 AWD655-10AE-SC-P16 AWD655-10A-2SC-P01 AWD655-10A-2SC-P02 AWD655-10A-2SC-P14 AWD655-10A-2SC-P15 AWD655-10A-2SC-P16 AWD655-10AE-2SC-P01 AWD655-10AE-2SC-P02 AWD655-10AE-2SC-P14 AWD655-10AE-2SC-P15 AWD655-10AE-2SC-P16 BASIC UDI-DI: 805673649AWD655FC	☐ 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 corre- sponding device under MDD/AIMDD Individual Article number: AWD655-10A-SC	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AWD655-10AD-P01 AWD655-10AD-P02 AWD655-10AD-P14 AWD655-10AD-P15 AWD655-10AD-P16 AWD655-10ADE-P01 AWD655-10ADE-P02	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	☐ N/A or ☒ Identification of the corre- sponding device under MDD/AIMDD	☒ Certification as follows: G1 041151 0014 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
AWD655-10ADE-P14 AWD655-10ADE-P15 AWD655-10ADE-P16 BASIC UDI-DI: 805673649AWD655FC	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number: AWD655-10AD	
AWD655-10AD-SC-P01 AWD655-10AD-SC-P02 AWD655-10AD-SC-P14 AWD655-10AD-SC-P15 AWD655-10AD-SC-P16 AWD655-10ADE-SC-P01 AWD655-10ADE-SC-P02 AWD655-10ADE-SC-P14 AWD655-10ADE-SC-P15 AWD655-10ADE-SC-P16 AWD655-10AD-2SC-P01 AWD655-10AD-2SC-P02 AWD655-10AD-2SC-P14 AWD655-10AD-2SC-P15 AWD655-10AD-2SC-P16 AWD655-10ADE-2SC-P01 AWD655-10ADE-2SC-P02 AWD655-10ADE-2SC-P14 AWD655-10ADE-2SC-P15 AWD655-10ADE-2SC-P16 BASIC UDI-DI: 805673649AWD655FC	☐ 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: AWD655-10AD-SC	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AWD655-10D-P01 AWD655-10D-P02 AWD655-10D-P14 AWD655-10D-P15 AWD655-10D-P16 AWD655-10DX-P01 AWD655-10DX-P02 AWD655-10DX-P14 AWD655-10DX-P15 AWD655-10DX-P16 AWD655-10DE-P01 AWD655-10DE-P02 AWD655-10DE-P14 AWD655-10DE-P15 AWD655-10DE-P16 AWD655-10DXE-P01	☐ 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: AWD655-10D	☒ Certification as follows: G1 041151 0014 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
AWD655-10DXE-P02 AWD655-10DXE-P14 AWD655-10DXE-P15 AWD655-10DXE-P16 BASIC UDI-DI: 805673649AWD655FC			
AWD655-10D-SC-P01 AWD655-10D-SC-P02 AWD655-10D-SC-P14 AWD655-10D-SC-P15 AWD655-10D-SC-P16 AWD655-10DX-SC-P01 AWD655-10DX-SC-P02 AWD655-10DX-SC-P14 AWD655-10DX-SC-P15 AWD655-10DX-SC-P16 AWD655-10DE-SC-P01 AWD655-10DE-SC-P02 AWD655-10DE-SC-P14 AWD655-10DE-SC-P15 AWD655-10DE-SC-P16 AWD655-10DXE-SC-P01 AWD655-10DXE-SC-P02 AWD655-10DXE-SC-P14 AWD655-10DXE-SC-P15 AWD655-10DXE-SC-P16 BASIC UDI-DI: 805673649AWD655FC	☐ 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: AWD655-10D-SC	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AWD655-15A-P17 AWD655-15AE-P17 BASIC UDI-DI: 805673649AWD655FC	☐ 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: AWD655-15A	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AWD655-15A-SC-P17 AWD655-15AE-SC-P17 AWD655-15A-2SC-P17	☐ Class III ☐ Class IIb implantable (non-exempted)	☐ N/A or	☒ Certification as follows: G1 041151 0014 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
AWD655-15AE-2SC-P17 AWD655-15A-3SC-P17 AWD655-15AE-3SC-P17 BASIC UDI-DI: 805673649AWD655FC	☒ 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: AWD655-15A-SC	
AWD655-15AD-P17 AWD655-15ADE-P17 BASIC UDI-DI: 805673649AWD655FC	☐ 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: AWD655-15AD	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AWD655-15AD-SC-P17 AWD655-15ADE-SC-P17 AWD655-15AD-2SC-P17 AWD655-15ADE-2SC-P17 AWD655-15AD-3SC-P17 AWD655-15ADE-3SC-P17 BASIC UDI-DI: 805673649AWD655FC	☐ 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: AWD655-15AD-SC	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
AF2.686SG AF2.686SAG AF2.686SV AF2.686SAV AF2.45SG Basic UDI-DI: 805673649AF2LK	☐ 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: AF2.686SG AF2.686SAG AF2.686SV AF2.686SAV AF2.45SG	☒ Certification as follows: G1 041151 0014 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
REVO REVO-PRO Basic UDI-DI: 805673649AF2LK	☐ 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 041151 0014 Rev. 00; NB# 0123
TIVA10-1M TIVA10-1M-1HS TIVA10-1M-1HS-E TIVA10-1M-1HS-X TIVA10-1M-1HS-XE TIVA10-1M-2HS TIVA10-1M-2HS-E TIVA10-1M-2HS-X TIVA10-1M-2HS-XE TIVA10-1M-E TIVA10-1M-X TIVA10-1M-XE TIVA10-1V TIVA10-1V-1HS TIVA10-1V-1HS-E TIVA10-1V-2HS TIVA10-1V-2HS-E TIVA10-1V-E TIVA10-2M TIVA10-2M-1HS TIVA10-2M-1HS-E TIVA10-2M-1HS-X TIVA10-2M-1HS-XE TIVA10-2M-2HS TIVA10-2M-2HS-E TIVA10-2M-2HS-X TIVA10-2M-2HS-XE TIVA10-2M-E TIVA10-2M-X TIVA10-2M-XE TIVA10-2V TIVA10-2V-1HS TIVA10-2V-1HS-E TIVA10-2V-2HS TIVA10-2V-2HS-E	☐ 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 041151 0014 Rev. 00; NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classifica- tion (as proposed by the manufacturer and verified during appli- cation review)	If the MDR device is a sub- stitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
TIVA10-2V-E TIVA15-1V TIVA15-1V-HS TIVA15-2V TIVA15-2V-HS TIVA2 TIVA2-E TIVA2-H TIVA2-HE TIVA2-HX TIVA2-HXE TIVA2-X TIVA2-XE TIVA8-1M TIVA8-E-1M TIVA8-WD-HS-1M TIVA8-WD-1M TIVA8-WD-E-1M TIVA8-WD-HS-E-1M TIVA8-WD-HS-X-1M TIVA8-WD-HS-XE-1M TIVA8-WD-X-1M TIVA8-WD-XE-1M TIVA8-X-1M TIVA8-XE-1M Basic UDI-DI: 805673649AF2LK			
SWD.8.1MD SWD.8.1MD.L SWD.8.1MD.SC.L SWD.12.1MD SWD.12.2MD SWD.12.1VD SWD.12.2VD SWD.12.1MD.SC SWD.12.2MD.SC SWD.12.1VD.SC SWD.12.2VD.SC SWD.18.1VD SWD.18.2VD SWD.18.1VD.SC SWD.18.2VD.SC Basic UDI-DI: 805673649AF2LK	☐ 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 corre- sponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 041151 0014 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
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-03-19	713294212; ITA1992645_CL	Initial issue
2024-06-24	ITA200220003828_CL	Addition of device (Basic UDI-DI 805673649AF2LK); removal of double entry on page 4
2024-10-07	ITA200220006001; 713349046	Addition of device families "REVO", "TIVA", and "SWD" (re-branding of already covered devices); Correction of classification of devices with Basic UDI-DI "805673649AWD655FC" – corrected from class IIa to class IIb