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TÜV SÜD

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

TÜV SÜD 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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Digitally signed by Lungu Ion
Date: 2024.10.05 14:22:55 EEST
Reason: MoldSign Signature
Location: Moldova
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Add value.
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TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
041151	713294212 ITA1992645_CL	+39 3489010334 Paolo.Bolelli@tuvsud.com		2024-03-19	1 of 23

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 041151 0015 Rev. 00

Reference: 713294212

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.

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 041151 0015 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-03-19

TÜV SÜD Product Service GmbH
Medical and Health Services

Paolo Bolelli
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Mar 19, 2024 09:51 GMT+1)

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**	
AF2.45MV-P17 **AF2.45MV-P21** **AF2.45MV-P23** **AF2.45MV-P19** **AF2.45MV-P11** **AF2.45MV-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: **AF2.45MV**	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
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**	☐ 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: **AF2.45PG**	
AF2.45PV-P17 **AF2.45PV-P21** **AF2.45PV-P23** **AF2.45PV-P19** **AF2.45PV-P11** **AF2.45PV-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: **AF2.45PV**	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
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**	☐ 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: **AF2.60METV**	
AF2.60MEV-P17 **AF2.60MEV-P21** **AF2.60MEV-P23** **AF2.60MEV-P19** **AF2.60MEV-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: **AF2.60MEV**	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
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**	☐ 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
AF2.60PEG-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: **AF2.60PEG**	
AF2.60PETG-P17 **AF2.60PETG-P21** **AF2.60PETG-P23** **AF2.60PETG-P19** **AF2.60PETG-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: **AF2.60PETG**	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
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**	☐ 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
AF2.60PG-P23 **AF2.60PG-P19** **AF2.60PG-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: **AF2.60PG**	NB# 0123
AF2.60PV-P17 **AF2.60PV-P21** **AF2.60PV-P23** **AF2.60PV-P19** **AF2.60PV-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: **AF2.60PV**	☒ Certification as follows: G1 041151 0014 Rev. 00; 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

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
AF2.60XMEV-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
AF2.60XMG-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	☐ 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

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		
AF2.60XPEV-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 ☐ Class III implantable custom-made-device	☐ 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
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	☐ 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

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		
AF2.90ATG-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 ☐ 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: **AF2.90ATG/860**	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
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:**	☐ 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: **AF2.90BAG**	
AF2.90BATG-P17 **AF2.90BATG-P21** **AF2.90BATG-P23** **AF2.90BATG-P19** **AF2.90BATG-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: **AF2.90BATG**	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
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**	☐ 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: **AF2.90BG**	
AF2.90BV-P17 **AF2.90BV-P21** **AF2.90BV-P23** **AF2.90BV-P19** **AF2.90BV-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: **AF2.90BV**	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
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**	☐ 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**	
AF2.90XBAG-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
AF2.90XBAV-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**	☐ 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
AF2.90XBV-P23 **AF2.90XBV-P19** **AF2.90XBV-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.X90BV**	NB# 0123
AWD655-2-P11 **AWD655-2-P10** **AWD655-2X-P11** **AWD655-2X-P10** **AWD655-2E-P11** **AWD655-2E-P10** **AWD655-2XE-P11** **AWD655-2XE-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: **AWD655-2**	☒ Certification as follows: G1 041151 0014 Rev. 00; 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**	☐ 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 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
AWD655-8XE-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** **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**	☐ 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**	☒ 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
AWD655-8EL-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** **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**	☐ 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
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:** **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**	☐ 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: **AWD655-10-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
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:** **805673649AWD655FC**	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
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 corresponding 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**	☐ 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: **AWD655-10A-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
AWD655-10AE-2SC-P15 **AWD655-10AE-2SC-P16** **BASIC UDI-DI:** **805673649AWD655FC**			
AWD655-10AD-P01 **AWD655-10AD-P02** **AWD655-10AD-P14** **AWD655-10AD-P15** **AWD655-10AD-P16** **AWD655-10ADE-P01** **AWD655-10ADE-P02** **AWD655-10ADE-P14** **AWD655-10ADE-P15** **AWD655-10ADE-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**	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
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**	☐ 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
AWD655-10D-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** **AWD655-10DXE-P02** **AWD655-10DXE-P14** **AWD655-10DXE-P15** **AWD655-10DXE-P16** **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: **AWD655-10D**	
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**	☐ 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
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: **AWD655-15A**	NB# 0123
AWD655-15A-SC-P17 **AWD655-15AE-SC-P17** **AWD655-15A-2SC-P17** **AWD655-15AE-2SC-P17** **AWD655-15A-3SC-P17** **AWD655-15AE-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: **AWD655-15A-SC**	☒ Certification as follows: G1 041151 0014 Rev. 00; NB# 0123
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

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

Manufacturer Declaration

Maia, 11th May 2021

We, PROHS – Equipamento Hospitalar e Serviços Associados S.A., manufacturer of medical devices for the sterilization and disinfection area, with factories in Rua do Castanhal n. 316, Zona Industrial da Maia I Sector II, 4476-908 Maia, Portugal, clarify that the Instruments Washer Disinfector range sold by PROHS is manufactured within an OBL contract with the reputable company AT-OS S.r.l., headquartered at Viale del lavoro, 19 37030 Colognola ai Colli, Verona, Italy.

Model equivalence table:

DESIGNATION	AT-OS SERIES	PROHS SERIES
Instruments Washer Disinfector	AWD655-10	PROHS WD 10
	AWD655-10-SC	PROHS WD 10 - SC
	AWD655-10D	PROHS WD 10D
	AWD655-10D-SC	PROHS WD 10D - SC
	AWD655-10A	PROHS WD 10A
	AWD655-10A-SC	PROHS WD 10A - SC
	AWD655-10AD	PROHS WD 10AD
	AWD655-10AD-SC	PROHS WD 10AD - SC
	AWD655-15A	PROHS WD 15A
	AWD655-15A-SC	PROHS WD 15A - SC
	AWD655-15AD	PROHS WD 15AD
	AWD655-15AD-SC	PROHS WD 15AD - SC
	AWD655-8	PROHS WD 8
	AWD655-8L	PROHS WD 8L
	AWD655-8L - SC	PROHS WD 8L SC

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Lorenzino Paolo
(CEO, AT-OS)

SGS certificação acreditada IPAC