AT-OS Srl | Viale del Lavoro, 19 - 37030 Colognola ai Colli - Verona - ITALY
Tel (+39) 045 6159411 - Fax (+39) 045 6159422
info@at-os.com | www.at-os.com
Partita IVA: IT 02719270239

DECLARATION OF CONFORMITY

Seller : TURKUAZ BIYOMEDIKAL TEKN. VE SAG. HIZM. SAN. TIC. LTD. STI.

KAZIM OZALP MAH. HAFTA SOK. NO: 23/2 06610 CANKAYA / ANKARA /TURKEY

Manufacturer : AT-OS S.r.l.

Viale del Lavoro, 19 Colognola ai Colli (VR) – Italy

We, as manufacturer of this product, herewith declare under our sole responsibility that the below mentioned products designed especially for the seller mentioned above:

Product : Machine for washing and disinfection

UMBNS Code : 17671

Model Code : PLUSHER WDC 8, PLUSHER WDS 12, PLUSHER WDS18

Classification : IIb (According to MDD, Annex IX)

meet the provisions of the following EC Council Directives and Standards. All supporting documentation's are retained under the premises of the manufacturer and the notified body.

Directives : Medical Device Directive – COUNCIL DIRECTIVE of 14 June 1993 concerning medical devices (MDD 93/42/EEC), Annex I; 2007/47/EEC: updating to Medical Device Directive 93/42/EEC.

Standards : Standards applicable to this product are EN ISO 13485:2012; DIN EN 1717:2001; DIN EN 13077:2004; EN 61010-1:2010; EN 61010-2-040:2005; EN 61326-1:2006 + Recommendation NB-MED/2.12 Rec 1; EN ISO 15883-1:2009; EN ISO 15883-2:2009.

Notified Body : TÜV SÜD Product Service GmbH.

Ridler Str. 65, D-80339 München, Germany

Conf. Asses. Route : Annex II.3.

AT-OS S.r.l.
Francesco Avesani
(Regulatory Office)

06.09.2017

Digitally signed by Bolea Petru
Date: 2026.06.08 10:44:11 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

TURQUOISE BIOMEDICAL TECHNOLOGIES

DECLARATION OF CONFORMITY

Seller : TURKUAZ BIYOMEDIKAL TEKN. VE SAG. HIZM. SAN. TIC. LTD. STI. (SRN: TR-MF-000037854)
KAZIM OZALP MAH. HAFTA SOK. NO: 23/2 06610 CANKAYA / ANKARA /TURKEY

Manufacturer : AT-OS S.r.l. (SRN: IT-MF-000028623)
Viale del Lavoro, 19 Colognola ai Colli (VR) – Italia

We, as seller of this product, herewith declare under our sole responsibility that the below mentioned products designed especially for the seller mentioned above:

Product : Washer Disinfector
GMDN Code : 66797 **Basic UDI-DI / GMN Code:** 868200922PLUSHER2H
Model Code :

Ref. No	Model	EMDN	Barcode (UDI-DI / GTIN)
311003	PLUSHER WDC 8	Z12011301	8681015020607
311004	PLUSHER WDC 8	Z12011301	8681015020614
311005	PLUSHER WDC 8	Z12011301	8682009204850
311006	PLUSHER WDS 12	Z12011301	8681015020621
311007	PLUSHER WDS 12	Z12011301	8682009204867
311008	PLUSHER WDS 12	Z12011301	8681015020638
311009	PLUSHER WDS 12	Z12011301	8682009204874
311010	PLUSHER WDS 12	Z12011301	8681015020645
311011	PLUSHER WDS 12	Z12011301	8682009204881
311012	PLUSHER WDS 12	Z12011301	8681015020652
311013	PLUSHER WDS 12	Z12011301	8682009204898
311014	PLUSHER WDS 18	Z12011301	8681015020669
311015	PLUSHER WDS 18	Z12011301	8682009204904
311016	PLUSHER WDS 18	Z12011301	8681015020676
311017	PLUSHER WDS 18	Z12011301	8682009204911
311021	PLUSHER WDC 2	Z12011301	8682009204928
311022	PLUSHER WDC 2	Z12011301	8682009204935

Classification : Medical Device Class IIb (MDR 2017/745, Annex VIII, Rule 16)

meet the provisions of the following EC Council Directives and Standards. All supporting documentation's are retained under the premises of the manufacturer and the notified body.

Standards : Standards applicable to this product are EN ISO 13485:2016; Regulation EU/2017/745, EN 1717, EN 61010-1, EN IEC 61010-2-040, EN IEC 61326-1, EN ISO 15883-1:2009+A1:2014, EN ISO 15883-2:2009, EN ISO 15883-5, EN ISO 20417, EN ISO 15223-1, EN ISO 14971, EN 62366-1.

Notified Body : TÜV SÜD Product Service GmbH. (ID: 0123)
Ridler Str. 65, D-80339 München, Germany

Conf. Asses. Route : This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex IX of the MDR. The conformity of the full quality assurance system set out in Annex IX, is described in the said CE Marking of Conformity Certificate, issued and delivered by TÜV SÜD Product Service GmbH (Id Cod 0123), certificate no. G10 041151 0016 Rev. 00.

TURKUAZ BİYOMEDİKAL TEKNOLOJİLER
VE SAĞ. HİZ. SAN. TİC. LTD. ŞTİ.
Kazım Özalp Mah. Hafta Sok. No: 23/2
G.O.P. - Çankaya / ANKARA / TURKEY
Tel: +90 850 840 8 828 Fax: +90 312 911 25 28
Cumhuriyet VD 471 052 4583
Mersis No: 0471052153300016

M. Hilmi MİRELİ
CEO
06.10.2025

Add value.
Inspire trust.

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; 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.

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

Paolo Bolelli
Paolo Bolelli (Oct 7, 2024 13:58 GMT+2)

Paolo Bolelli
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

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 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
AWD655-8E-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 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
AWD655-8XL-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 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			
AWD655-10A-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** **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 corresponding 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 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
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 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
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 corresponding 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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 041151 0016 Rev. 00

Manufacturer:

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

SRN Manufacturer - IT-MF-000028623

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 041151 0016 Rev. 00

Report No.: ITA1992645

Valid from: 2025-03-07
Valid until: 2030-03-06

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-03-07

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 041151 0016 Rev. 00

Classification:	Class IIa
Device Group:	Z12011301 - CLEANING AND DISINFECTION EQUIPMENT
Intended Purpose:	\

Classification:	Class IIb
Device Group:	Z12011301 - CLEANING AND DISINFECTION EQUIPMENT
Intended Purpose:	The washer disinfector is designed for the needs of cleaning and disinfecting non active and active surgical instruments, whose manufacturers expressly state that they can be treated in the machine. Non active surgical instruments, such as: dental instruments; instruments for surgery and minimally invasive surgery (MIS); anesthesia and intensive care instruments; surgical instruments for ophthalmology; instruments for arthroscopy and rectoscopy (except for flexible endoscopes); instruments for ear, nose and throat surgery; instruments for gynaecology and urology; baby bottles and teats; ward end utensils such as kidney dishes, bowls. And accessories of active surgical instruments: dental handpieces or Da Vinci arms.

The validity of this certificate depends on conditions and/or is limited to the following:	\

Revision History:

Rev.	Dated	Report	Description
00	2025-03-07	ITA1992645	Initial issuance

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

SQR CERTIFICATION

Sertifika
CERTIFICATE

TURKUAZ BİYOMEDİKAL TEKNOLOJİLER VE SAĞLIK HİZMETLERİ SAN. TİC. LTD. ŞTİ.

KAZIM ÖZALP MAH. HAFTA SOK. NO: 23/2 ÇANKAYA/ANKARA/TÜRKİYE

ISO 9001:2015

Kapsam/Scope

BUHAR STERİLİZATÖRLERİNİN, PLAZMA STERİLİZATÖRLERİ VE SARFLARININ, LTSF STERİLİZATÖRLERİNİN, OTOKLAVLARIN, YIKAMA VE DEZENFEKSİYON CİHAZLARININ, ULTRASONİK YIKAYICILARIN, POŞET KAPAMA CİHAZLARININ, ETİLEN OKSİT STERİLİZATÖRLERİNİN, HASTANE PASLANMAZ EKİPMANLARININ, KONTEYNER SİSTEMLERİ VE AKSESUARLARININ, YIKAMA VE STERİLİZASYON KONTROL ÜRÜNLERİNİN, STERİLİZASYON RULOLARI VE POŞETLERİNİN, BOWIE-DICK TEST PAKETLERİNİN, KİMYASAL İNDİKATÖRLERİN, BİYOLOJİK İNDİKATÖRLERİN, OTOKLAV BANTLARININ, KREPE KAĞITLARININ VE DEZENFEKTAN VE DETERJANLARIN DİZAYNI, GELİŞTİRMESİ, ÜRETİMİ, SATIŞI VE SERVİSİ

DESIGN, DEVELOPMENT, PRODUCTION, SALES AND SERVICE OF STEAM STERILIZERS, PLASMA STERILIZERS & DISPOSABLES, LTSF STERILIZERS, AUTOCLAVES, WASHER DISINFECTORS, ULTRASONIC CLEANERS, SEALERS, ETHYLENE OXIDE STERILIZERS, STAINLESS HOSPITAL EQUIPMENTS, CONTAINER SYSTEMS & ACCESSORIES, STERILIZATION & WASHING CONTROL PRODUCTS, STERILIZATION ROLLS AND POUCHES, BOWIE-DICK TEST PACKAGES, CHEMICAL INDICATORS, BIOLOGICAL INDICATORS, AUTOCLAVE TAPES, WRAPPING PAPERS AND DISINFECTANTS & DETERGENTS

IAF KOD:7-12-14-17-18-19-23

Bu sertifika ile yukarıda adı geçen kuruluşun Kalite Yönetim Sistemi gerekliliklerini karşıladığı tasdik olunur.

This is to certify that the above mentioned company meets the requirement of Quality Management System.

Sertifika No / Certification Number	: MTS-49241
İlk Kayıt Tarihi / Date of Initial Reg.	: 12.03.2026
Basım Tarihi / Date of Certificate	: 12.03.2026
Geçerlilik Tarihi / Date of Expiry	: 11.03.2027
Revizyon / Revision	: 008

Bu sertifika kuruluşun belgelendirme şartlarına uyması ve yılda en az 1 kez yapılacak olan gözetim denetimlerinin başarılı geçmesi halinde üç yıllık sertifikasyon periyodu bitiş tarihine kadar geçerlidir.

This certificate is valid until the end of the three-year certification period if the organization complies with the certification requirements and the surveillance audits to be carried out at least once a year are completed successfully.

Genel Müdür Yardımcısı / Deputy General Manager

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

IAS ACCREDITED Management Systems Certification Body MSCB-136

SIGMACERT DOO
Gavra Vukovića BB Podgorica, Montenegro
belgelendirme@sigmacert.com.tr +38268118852

CERTIFICATE

TURKUAZ BİYOMEDİKAL TEKNOLOJİLER VE SAĞLIK HİZMETLERİ SAN. TİC. LTD. ŞTİ.

KAZIM ÖZALP MAH. HAFTA SOK. NO: 23/2 ÇANKAYA / ANKARA / TÜRKİYE

Has been independently audited and found to comply with the requirements of the following standard.

Bağımsız olarak denetlenmiş ve aşağıdaki standardın gerekliliklerine uygun olduğu görülmüştür.

ISO 10002:2018

The Customer Satisfaction Management System is applicable to:

Müşteri Memnuniyeti Yönetim Sistemi:

This certificate is given within the scope of the below:

DESIGN, DEVELOPMENT, PRODUCTION, SALES AND SERVICE OF STEAM STERILIZERS, PLASMA STERILIZERS& DISPOSABLES, LTSF STERILIZERS, AUTOCLAVES, WASHER DISINFECTORS, ULTRASONIC CLEANERS, SEALERS, ETHYLENE OXIDE STERILIZERS, STAINLESS HOSPITAL EQUIPMENTS, CONTAINER SYSTEMS & ACCESSORIES, STERILIZATION & WASHING CONTROL PRODUCTS, STERILIZATION ROLLS AND POUCHES, BOWIE-DICK TEST PACKAGES, CHEMICAL INDICATORS, BIOLOGICAL INDICATORS, AUTOCLAVE TAPES,WRAPPING PAPERS AND DISINFECTANTS & DETERGENTS

Bu sertifika aşağıdaki kapsam dahilinde verilmiştir.

BUHAR STERİLİZATÖRLERİNİN, PLAZMA STERİLİZATÖRLERİ VE SARFLARININ, LTSF STERİLİZATÖRLERİNİN, OTOKLAVLARIN, YIKAMA VE DEZENFEKSİYON CİHAZLARININ, ULTRASONİK YIKAYICILARIN, POŞET KAPAMA CİHAZLARININ, ETİLEN OKSİT STERİLİZATÖRLERİNİN, HASTANE PASLANMAZ EKİPMANLARININ, KONTEYNER SİSTEMLERİ VE AKSESUARLARININ, YIKAMA VE STERİLİZASYON KONTROL ÜRÜNLERİNİN, STERİLİZASYON RULOLARI VE POŞETLERİNİN, BOWIE-DICK TEST PAKETLERİNİN, KİMYASAL İNDİKATÖRLERİN, BİYOLOJİK İNDİKATÖRLERİN, OTOKLAV BANTLARININ, KREPE KAĞITLARININ VE DEZENFEKTAN VE DETERJANLARIN DİZAYNI, GELİŞTİRMESİ, ÜRETİMİ, SATIŞI VE SERVİSİ

Certificate Number	:	**D44027N**	Sertifika No
Certificate Initial Issue Date	:	**10.01.2024**	Sertifika İlk Düzenleme Tarihi
Certificate Issue Date	:	**10.01.2026**	Sertifika Düzenleme Tarihi
Certificate Validity Date	:	**09.01.2027**	Sertifika Geçerlilik Tarihi
Certification Period	:	**3 Years**	Belgelendirme Periyodu
Revision Number	:	**00**	Revizyon No

Certificate validity information **www.dcscertification.com** you can check at. DCS CERTIFICATION INSPECTION PRIVATE COMPANY D-17, Daliganj, Lucknow, Uttar Pradesh 226020, India Web: **www.dcscertification.com** • E-Mail: **info@dcscertification.com**

CERTIFICATION MANAGER

TURQUOISE BIOMEDICAL TECHNOLOGIES

DECLARATION OF CONFORMITY

Seller : TURKUAZ BIYOMEDIKAL TEKN. VE SAG. HIZM. SAN. TIC. LTD. STI.

KAZIM OZALP MAH. HAFTA SOK. NO: 23/2 06610 CANKAYA / ANKARA /TURKEY

Manufacturer : AT-OS S.r.l.

Viale del Lavoro, 19 Colognola ai Colli (VR) – Italia

We, as seller of this product, herewith declare under our sole responsibility that the below mentioned products designed especially for the seller mentioned above:

Product : Machine for washing and disinfection

UMBNS Code : 17671

Model Code : PLUSHER WDC 8, PLUSHER WDS 12, PLUSHER WDS18

Classification : IIb (According to MDD, Annex IX)

meet the provisions of the following EC Council Directives and Standards. All supporting documentation's are retained under the premises of the manufacturer and the notified body.

Directives : Medical Device Directive – COUNCIL DIRECTIVE of 14 June 1993 concerning medical devices (MDD 93/42/EEC), Annex I; 2007/47/EEC: updating to Medical Device Directive 93/42/EEC.

Standards : Standards applicable to this product are EN ISO 13485:2012; DIN EN 1717:2001; DIN EN 13077:2004; EN 61010-1:2010; EN 61010-2-040:2005; EN 61326-1:2006 + Recommendation NB-MED/2.12 Rec 1; EN ISO 15883-1:2009; EN ISO 15883-2:2009.

Notified Body : TÜV SÜD Product Service GmbH.

Ridler Str. 65, D-80339 München, Germany

Conf. Asses. Route : Annex II.3.

TURKUAZ BİYOMEDİKAL TEKNOLOJİLER
VE SAĞ. HİZ. SAN. TİC. LTD. ŞTİ.
Kazım Özalp Mah. Hafta Sok. No: 23/2
G.O.P. - Çankaya / ANKARA / TURKEY
Tel: +90 850 840 8 828 Fax: +90 312 911 25 28
Cumhuriyet V.D. 0671052 4583
Mersis No: 0671052153300016

M. Hilmi MİRELİ
CEO
06.09.2017

CERTIFICATE

TURKUAZ BİYOMEDİKAL TEKNOLOJİLER VE SAĞLIK HİZMETLERİ SAN. TİC. LTD. ŞTİ.

KAZIM ÖZALP MAH. HAFTA SOK. NO:23/2
ÇANKAYA / ANKARA / TÜRKİYE

Has been assessed and found to comply with the requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 13485:2016

Medical Devices-Quality Management System is applicable to:
Tıbbi Cihazlar Kalite Yönetim Sistemi

DESIGN, DEVELOPMENT, MANUFACTURE, SALES AND SERVICE OF STEAM STERILISERS, PLASMA STERILISERS AND CONSUMABLES, LTSF STERILISERS, AUTOCLAVES, WASHING AND DISINFECTION DEVICES, ULTRASONIC WASHERS, BAG SEALING DEVICES, ETHYLENE OXIDE STERILISERS, HOSPITAL STAINLESS EQUIPMENT, CONTAINER SYSTEMS AND ACCESSORIES, STERILISATION ROLLS AND BAGS, AUTOCLAVE TAPES, CREPE PAPER, DISINFECTANTS AND DETERGENTS FOR THE MEDICAL SECTOR, SALES OF WASHING AND STERILISATION CONTROL PRODUCTS, BOWIE-DICK TEST PACKAGES, CHEMICAL INDICATORS, BIOLOGICAL INDICATORS

MEDİKAL SEKTÖRE YÖNELİK BUHAR STERİLİZATÖRLERİNİN, PLAZMA STERİLİZATÖRLERİ VE SARFLARININ, LTSF STERİLİZATÖRLERİNİN, OTOKLAVLARIN, YIKAMA VE DEZENFEKSİYON CİHAZLARININ, ULTRASONİK YIKAYICILARIN, POŞET KAPAMA CİHAZLARININ, ETİLEN OKSİT STERİLİZATÖRLERİNİN, HASTANE PASLANMAZ EKİPMANLARININ, KONTEYNER SİSTEMLERİ VE AKSESUARLARININ, STERİLİZASYON RULOLARI VE POŞETLERİNİN, OTOKLAV BANTLARININ, KREPE KAĞITLARININ VE DEZENFEKTAN VE DETERJANLARIN DİZAYNI, GELİŞTİRMESİ, ÜRETİMİ, SATIŞI VE SERVİSİ, YIKAMA VE STERİLİZASYON KONTROL ÜRÜNLERİNİN, BOWIE-DICK TEST PAKETLERİNİN, KİMYASAL İNDİKATÖRLERİN, BİYOLOJİK İNDİKATÖRLERİN SATIŞI

Certificate Number: 2025/MDQMS/000896 **Initial Certification Date: 14.03.2025**
Belge Numarası: 2025/MDQMS/000896 **İlk Belgelendirme Tarihi: 14.03.2025**

Certification Period: 3 Years **Certificate Validity Date: 13.03.2027**
Belgelendirme Periyodu: 3 Yıl **Belge Geçerlilik Tarihi: 13.03.2027**

IAS ACCREDITED Management Systems Certification Body MSCB-135

IQR Certification Approval

IQR INTERNATIONAL CERTIFICATION SERVICES LLC
8 The Green Suite A, Dover, Delaware 19901, USA
www.iqrcert.com | e-posta: info@iqrcert.com

SQR CERTIFICATION

Sertifika
CERTIFICATE

TURKUAZ BİYOMEDİKAL TEKNOLOJİLER VE SAĞLIK HİZMETLERİ SAN. TİC. LTD. ŞTİ.

KAZIM ÖZALP MAH. HAFTA SOK. NO: 23/2 ÇANKAYA/ANKARA/TÜRKİYE

ISO 14001:2015

Kapsam/Scope

BUHAR STERİLİZATÖRLERİNİN, PLAZMA STERİLİZATÖRLERİ VE SARFLARININ, LTSF STERİLİZATÖRLERİNİN, OTOKLAVLARIN, YIKAMA VE DEZENFEKSİYON CİHAZLARININ, ULTRASONİK YIKAYICILARIN, POŞET KAPAMA CİHAZLARININ, ETİLEN OKSİT STERİLİZATÖRLERİNİN, HASTANE PASLANMAZ EKİPMANLARININ, KONTEYNER SİSTEMLERİ VE AKSESUARLARININ, YIKAMA VE STERİLİZASYON KONTROL ÜRÜNLERİNİN, STERİLİZASYON RULOLARI VE POŞETLERİNİN, BOWIE-DICK TEST PAKETLERİNİN, KİMYASAL İNDİKATÖRLERİN, BİYOLOJİK İNDİKATÖRLERİN, OTOKLAV BANTLARININ, KREPE KAĞITLARININ VE DEZENFEKTAN VE DETERJANLARIN DİZAYNI, GELİŞTİRMESİ, ÜRETİMİ, SATIŞI VE SERVİSİ

DESIGN, DEVELOPMENT, PRODUCTION, SALES AND SERVICE OF STEAM STERILIZERS, PLASMA STERILIZERS & DISPOSABLES, LTSF STERILIZERS, AUTOCLAVES, WASHER DISINFECTORS, ULTRASONIC CLEANERS, SEALERS, ETHYLENE OXIDE STERILIZERS, STAINLESS HOSPITAL EQUIPMENTS, CONTAINER SYSTEMS & ACCESSORIES, STERILIZATION & WASHING CONTROL PRODUCTS, STERILIZATION ROLLS AND POUCHES, BOWIE-DICK TEST PACKAGES, CHEMICAL INDICATORS, BIOLOGICAL INDICATORS, AUTOCLAVE TAPES, WRAPPING PAPERS AND DISINFECTANTS & DETERGENTS

IAF KOD:7-12-14-17-18-19-23

Bu sertifika ile yukarıda adı geçen kuruluşun Çevre Yönetim Sistemi gerekliliklerini karşıladığı tasdik olunur.

This is to certify that the above mentioned company meets the requirement of Environmental Management System.

Sertifika No / Certification Number	: MTS-49242
İlk Kayıt Tarihi / Date of Initial Reg.	: 12.03.2026
Basım Tarihi / Date of Certificate	: 12.03.2026
Geçerlilik Tarihi / Date of Expiry	: 11.03.2027
Revizyon / Revision	: 008

Bu sertifika kuruluşun belgelendirme şartlarına uyması ve yılda en az 1 kez yapılacak olan gözetim denetimlerinin başarılı geçmesi halinde üç yıllık sertifikasyon periyodu bitiş tarihine kadar geçerlidir.
This certificate is valid until the end of the three-year certification period if the organization complies with the certification requirements and the surveillance audits to be carried out at least once a year are completed successfully.

Genel Müdür Yardımcısı // Deputy General Manager

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

IAS ACCREDITED Management Systems Certification Body MSCB-136

SIGMACERT DOO
Gavra Vukovića BB Podgorica, Montenegro
belgelendirme@sigmacert.com.tr +38268118852

CERTIFICATE

TURKUAZ BİYOMEDİKAL TEKNOLOJİLER VE SAĞLIK HİZMETLERİ SAN. TİC. LTD. ŞTİ.

KAZIM ÖZALP MAH. HAFTA SOK. NO: 23/2 ÇANKAYA / ANKARA / TÜRKİYE

Has been independently audited and found to comply with the requirements of the following standard.

Bağımsız olarak denetlenmiş ve aşağıdaki standardın gerekliliklerine uygun olduğu görülmüştür.

ISO / IEC 27001:2022

The Information Security Management System is applicable to:

Bilgi Güvenliği Yönetim Sistemi:

This certificate is given within the scope of the below:

DESIGN, DEVELOPMENT, PRODUCTION, SALES AND SERVICE OF STEAM STERILIZERS, PLASMA STERILIZERS& DISPOSABLES, LTSF STERILIZERS, AUTOCLAVES, WASHER DISINFECTORS, ULTRASONIC CLEANERS, SEALERS, ETHYLENE OXIDE STERILIZERS, STAINLESS HOSPITAL EQUIPMENTS, CONTAINER SYSTEMS & ACCESSORIES, STERILIZATION & WASHING CONTROL PRODUCTS, STERILIZATION ROLLS AND POUCHES, BOWIE-DICK TEST PACKAGES, CHEMICAL INDICATORS, BIOLOGICAL INDICATORS, AUTOCLAVE TAPES,WRAPPING PAPERS AND DISINFECTANTS & DETERGENTS

Bu sertifika aşağıdaki kapsam dahilinde verilmiştir.

BUHAR STERİLİZATÖRLERİNİN, PLAZMA STERİLİZATÖRLERİ VE SARFLARININ, LTSF STERİLİZATÖRLERİNİN, OTOKLAVLARIN, YIKAMA VE DEZENFEKSİYON CİHAZLARININ, ULTRASONİK YIKAYICILARIN, POŞET KAPAMA CİHAZLARININ, ETİLEN OKSİT STERİLİZATÖRLERİNİN, HASTANE PASLANMAZ EKİPMANLARININ, KONTEYNER SİSTEMLERİ VE AKSESUARLARININ, YIKAMA VE STERİLİZASYON KONTROL ÜRÜNLERİNİN, STERİLİZASYON RULOLARI VE POŞETLERİNİN, BOWIE-DICK TEST PAKETLERİNİN, KİMYASAL İNDİKATÖRLERİN, BİYOLOJİK İNDİKATÖRLERİN, OTOKLAV BANTLARININ, KREPE KAĞITLARININ VE DEZENFEKTAN VE DETERJANLARIN DİZAYNI, GELİŞTİRMESİ, ÜRETİMİ, SATIŞI VE SERVİSİ

Applicability Statement / Uygulanabilirlik Bildirgesi: **SOA.00 Rev 00/12.02.2022**

Certificate Number	:	**D44025W**	Sertifika No
Certificate Initial Issue Date	:	**10.01.2024**	Sertifika İlk Düzenleme Tarihi
Certificate Issue Date	:	**10.01.2026**	Sertifika Düzenleme Tarihi
Certificate Validity Date	:	**09.01.2027**	Sertifika Geçerlilik Tarihi
Certification Period	:	**3 Years**	Belgelendirme Periyodu
Revision Number	:	**00**	Revizyon No

Certificate validity information **www.dcscertification.com** you can check at. DCS CERTIFICATION INSPECTION PRIVATE COMPANY D-17, Daliganj, Lucknow, Uttar Pradesh 226020, India Web: **www.dcscertification.com** • E-Mail: **info@dcscertification.com**

ISO/IEC 17021-1:2015 MANAGEMENT SYSTEM ACCREDITATION BODI NUMBER ABN-017

CERTIFICATION MANAGER

SQR CERTIFICATION

Sertifika
CERTIFICATE

TURKUAZ BİYOMEDİKAL TEKNOLOJİLER VE SAĞLIK HİZMETLERİ SAN. TİC. LTD. ŞTİ.

KAZIM ÖZALP MAH. HAFTA SOK. NO: 23/2 ÇANKAYA/ANKARA/TÜRKİYE

ISO 45001:2018

Kapsam/Scope

BUHAR STERİLİZATÖRLERİNİN, PLAZMA STERİLİZATÖRLERİ VE SARFLARININ, LTSF STERİLİZATÖRLERİNİN, OTOKLAVLARIN, YIKAMA VE DEZENFEKSİYON CİHAZLARININ, ULTRASONİK YIKAYICILARIN, POŞET KAPAMA CİHAZLARININ, ETİLEN OKSİT STERİLİZATÖRLERİNİN, HASTANE PASLANMAZ EKİPMANLARININ, KONTEYNER SİSTEMLERİ VE AKSESUARLARININ, YIKAMA VE STERİLİZASYON KONTROL ÜRÜNLERİNİN, STERİLİZASYON RULOLARI VE POŞETLERİNİN, BOWIE-DICK TEST PAKETLERİNİN, KİMYASAL İNDİKATÖRLERİN, BİYOLOJİK İNDİKATÖRLERİN, OTOKLAV BANTLARININ, KREPE KAĞITLARININ VE DEZENFEKTAN VE DETERJANLARIN DİZAYNI, GELİŞTİRMESİ, ÜRETİMİ, SATIŞI VE SERVİSİ

DESIGN, DEVELOPMENT, PRODUCTION, SALES AND SERVICE OF STEAM STERILIZERS, PLASMA STERILIZERS & DISPOSABLES, LTSF STERILIZERS, AUTOCLAVES, WASHER DISINFECTORS, ULTRASONIC CLEANERS, SEALERS, ETHYLENE OXIDE STERILIZERS, STAINLESS HOSPITAL EQUIPMENTS, CONTAINER SYSTEMS & ACCESSORIES, STERILIZATION & WASHING CONTROL PRODUCTS, STERILIZATION ROLLS AND POUCHES, BOWIE-DICK TEST PACKAGES, CHEMICAL INDICATORS, BIOLOGICAL INDICATORS, AUTOCLAVE TAPES, WRAPPING PAPERS AND DISINFECTANTS & DETERGENTS

IAF KOD:7-12-14-17-18-19-23

Bu sertifika ile yukarıda adı geçen kuruluşun İş Sağlığı ve Güvenliği Yönetim Sistemi gerekliliklerini karşıladığı tasdik olunur.

This is to certify that the above mentioned company meets the requirement of Occupational Health & Safety Management System.

Sertifika No / Certification Number	: MTS-42480
İlk Kayıt Tarihi / Date of Initial Reg.	: 25.12.2024
Basım Tarihi / Date of Certificate	: 28.01.2026
Geçerlilik Tarihi / Date of Expiry	: 24.12.2026
Revizyon / Revision	: 001

Bu sertifika kuruluşun belgelendirme şartlarına uyması ve yılda en az 1 kez yapılacak olan gözetim denetimlerinin başarılı geçmesi halinde üç yıllık sertifikasyon periyodu bitiş tarihine kadar geçerlidir.

This certificate is valid until the end of the three-year certification period if the organization complies with the certification requirements and the surveillance audits to be carried out at least once a year are completed successfully.

Genel Müdür Yardımcısı // Deputy General Manager

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

IAS ACCREDITED Management Systems Certification Body MSCB-136

SIGMACERT DOO
Gavra Vukovića BB Podgorica, Montenegro
belgelendirme@sigmacert.com.tr +38268118852

CERTIFICATE

TURKUAZ BİYOMEDİKAL TEKNOLOJİLER VE SAĞLIK HİZMETLERİ SAN. TİC. LTD. ŞTİ.

KAZIM ÖZALP MAH. HAFTA SOK. NO: 23/2 ÇANKAYA / ANKARA / TÜRKİYE

Has been independently audited and found to comply with the requirements of the following standard.

Bağımsız olarak denetlenmiş ve aşağıdaki standardın gerekliliklerine uygun olduğu görülmüştür.

ISO 50001:2018

The Energy Management System is applicable to:

Enerji Yönetim Sistemi:

This certificate is given within the scope of the below:

DESIGN, DEVELOPMENT, PRODUCTION, SALES AND SERVICE OF STEAM STERILIZERS, PLASMA STERILIZERS& DISPOSABLES, LTSF STERILIZERS, AUTOCLAVES, WASHER DISINFECTORS, ULTRASONIC CLEANERS, SEALERS, ETHYLENE OXIDE STERILIZERS, STAINLESS HOSPITAL EQUIPMENTS, CONTAINER SYSTEMS & ACCESSORIES, STERILIZATION & WASHING CONTROL PRODUCTS, STERILIZATION ROLLS AND POUCHES, BOWIE-DICK TEST PACKAGES, CHEMICAL INDICATORS, BIOLOGICAL INDICATORS, AUTOCLAVE TAPES,WRAPPING PAPERS AND DISINFECTANTS & DETERGENTS

Bu sertifika aşağıdaki kapsam dahilinde verilmiştir.

BUHAR STERİLİZATÖRLERİNİN, PLAZMA STERİLİZATÖRLERİ VE SARFLARININ, LTSF STERİLİZATÖRLERİNİN, OTOKLAVLARIN, YIKAMA VE DEZENFEKSİYON CİHAZLARININ, ULTRASONİK YIKAYICILARIN, POŞET KAPAMA CİHAZLARININ, ETİLEN OKSİT STERİLİZATÖRLERİNİN, HASTANE PASLANMAZ EKİPMANLARININ, KONTEYNER SİSTEMLERİ VE AKSESUARLARININ, YIKAMA VE STERİLİZASYON KONTROL ÜRÜNLERİNİN, STERİLİZASYON RULOLARI VE POŞETLERİNİN, BOWIE-DICK TEST PAKETLERİNİN, KİMYASAL İNDİKATÖRLERİN, BİYOLOJİK İNDİKATÖRLERİN, OTOKLAV BANTLARININ, KREPE KAĞITLARININ VE DEZENFEKTAN VE DETERJANLARIN DİZAYNI, GELİŞTİRMESİ, ÜRETİMİ, SATIŞI VE SERVİSİ

Certificate Number	:	**D44026W**	Sertifika No
Certificate Initial Issue Date	:	**10.01.2024**	Sertifika İlk Düzenleme Tarihi
Certificate Issue Date	:	**10.01.2026**	Sertifika Düzenleme Tarihi
Certificate Validity Date	:	**09.01.2027**	Sertifika Geçerlilik Tarihi
Certification Period	:	**3 Years**	Belgelendirme Periyodu
Revision Number	:	**00**	Revizyon No

Certificate validity information **www.dcscertification.com** you can check at. DCS CERTIFICATION INSPECTION PRIVATE COMPANY
D-17, Daliganj, Lucknow, Uttar Pradesh 226020, India Web: **www.dcscertification.com** • E-Mail: **info@dcscertification.com**

WQCAS

ISO/IEC 17021-1:2015 MANAGEMENT SYSTEM ACCREDITATION BODI NUMBER ABN-017

CERTIFICATION MANAGER

TURQUOISE BIOMEDICAL TECHNOLOGIES

DECLARATION OF CONFORMITY

Legal Manufacturer : TURKUAZ BIYOMEDIKAL TEKN. VE SAG. HIZM. SAN. TIC. LTD. STI. (TBT Medical)

KAZIM OZALP MAH. HAFTA SOK. NO: 23/2 06610 CANKAYA / ANKARA /TURKEY

We, TBT Medical hereby declare under our sole responsibility that the below mentioned devices:

Device(s) : PLUSEAL Series Rotary Sealers

GMDN Code : 36674 **Basic UDI-DI / GMN Code** : 868200922PLUSEALZ7

Reference No(s) :

Ref. No	EMDN	Barcode (UDI-DI / GTIN)
321002	S010399	8682009207820
321003	S010399	8682009207837
321004	S010399	8682009207844
321005	S010399	8682009207851
321006	S010399	8682009207868
321007	S010399	8682009207875

Classification : Not classified as a medical device under the clause of Medical Device Regulation (EU) 2017/745

meet the provisions of the following Regulation & Standards. This declaration is supported by the Quality Management System according to EN ISO 13485:2016. All supporting documentations are retained under the premises of the manufacturer.

Regulations : Machinery Directive 2006/42/EC, Low Voltage Directive 2014/35/EU, Electromagnetic Compatibility Directive 2014/30/EU, Waste Electrical and electronic Equipment Directive 2012/19/EU and Restriction of Hazardous Substances Directive 2015/863/EU

Standards : EN 60204-1:2018, EN 61000-6-1:2019, EN 61000-6-3:2021, EN ISO 13857:2019, EN IEC 63000:2018, EN 62304:2006, EN 62366-1:2015, EN 60529:1991, EN 60601-1-6:2010, EN 60601-1-8:2007, EN ISO 20417:2021, EN ISO 12100:2010, EN ISO 11607-2:2020 *(excl. 321002 & 321003)*, EN ISO 15223-1:2021, EN ISO 13485:2016, EN ISO 9001:2015, EN ISO 14001:2015 and EN ISO 45001:2018

Conf. Asses. Route : Machinery Directive 2006/42/EC

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