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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 091264 0016 Rev. 03

Holder of Certificate: **Edan Instruments, Inc.**
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Digitally signed by Bolea Petru
Date: 2026.01.19 16:46:53 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Scope of Certificate:

Design and Development, Production and Distribution of Transcranial Doppler System, Fetal Monitor, Fetal & Maternal Monitor, Patient Monitor, Central Monitoring System, Ultrasonic Pocket Doppler, Electrocardiograph, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, STRESS ECG, PC ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Data Management Software, Trolley (for medical use), ECG Electrode, Holter System, Treadmill (for medical use), Diagnostic Ultrasound System, Ultrasonic Imaging Management System, Blood Gas and Chemistry Analysis System (Including Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge, Controls, External Electronic Simulator, Capillary Adaptor, Ampoule adaptor), Hematology Analyzer, Reagents for Hematology Analyzer (Including Diluent, Lyse, Cleaner, Bleach, Hematology Control, Hematology Calibrator), Video Colposcope, Ultrasonic Transducer, TOCO Transducer, SPO2 Sensor, Temperature Probe, ECG Cable, Telemetry Transmitter, NIBP Cuff, Specific Protein Immunoassay System (Including Protein Assay Kit, Assay Buffer, Sample Dilution Buffer, Washing Buffer, Protein Analyzer), Biofeedback and Stimulation System, EMG/ Stimulation Sensor, Ambulatory Blood Pressure Monitor, NIBP Tube, Connection Cable, Water Trap, Needle Guide Bracket, ECG Analysis Software, Fetal Telemetry System, Electrosurgical Generator.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 091264 0016 Rev. 03

Report No.: BJ22089102
Valid from: 2022-12-01
Valid until: 2025-11-30

Date, 2022-08-18

Christoph Dicks
Head of Certification/Notified Body

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

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TÜV SÜD Product Service

Certificate

No. Q5 091264 0016 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

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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-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class D Devices, Class C and B Devices for self-/near-patient testing, Class C Devices Companion Diagnostics)

No. V10 091264 0062 Rev. 00

Manufacturer:

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000009957

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

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 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s). The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit 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 certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to the applicable Section(s) of Annex IX Chapter II is necessary in addition to this EU Quality Management System Certificate.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V10 091264 0062 Rev. 00

Report No.: BJ21089108

Valid from: 2023-11-06

Valid until: 2028-11-05

Marta Carnielli
Head of Certification IVD

Issue date: 2023-11-06

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class D Devices, Class C and B Devices for self-/near-patient testing,
Class C Devices Companion Diagnostics)

No. V10 091264 0062 Rev. 00

Classification:	Class B
Device Group:	W01010606 - ELECTRODES OR CASSETTES FOR BLOOD GAS ANALYSIS INCL. ELECTROLYTES / METABOLITES - POC
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
Classification:	Class C
Device Group:	W01010606 - ELECTRODES OR CASSETTES FOR BLOOD GAS ANALYSIS INCL. ELECTROLYTES / METABOLITES - POC
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
Classification:	Class C
Device Group:	W0101050204 - ELECTROLYTE CONTROLS
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
Classification:	Class C
Device Group:	W0101050301 - CALIBRATORS MULTICOMPONENT (CC)
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2023-11-06	BJ21089108	Initial issuance

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