



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Edan Instruments, Inc.

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District
Shenzhen, P.R. China
Post Code: 518122

Unified social credit code: 914403001923672010

has established and applies
a Quality Management System for

Design and Development, Production and Service, Distribution of non-implantable medical devices, In vitro diagnostic medical devices and reagents, software for medical industry, veterinary products, and their related electronic products, accessories, consumables.

An audit was performed, Order No. **748351674**.

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2022-08-16** until **2024-09-12**.

The certified organization shall undergo and pass
the regular surveillance audit to maintain the validity of this certificate.

Certificate Registration No.: **12 100 61404 TMS**.

Information about this certificate can be inquired at the official website
of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

Head of Certification Body
Munich, 2022-08-18



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Certificate

No. Q5 091264 0016 Rev. 04

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:



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, Holter ECG and ABP System, Blood Sampler, Molecular Diagnostic System (including Molecular Diagnostic Analyzer, Test Kit, Sample Collection Tube), Colloidal Gold Immunosassay Analyzer, Blood Pressure Monitor

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. 04

Report No.: BJ22089104
Valid from: 2023-06-26
Valid until: 2025-11-30

Date, 2023-06-26



Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 091264 0016 Rev. 04

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



CERTIFICATE OF TRAINING

Sergiu Sorocovici,

From "GBG-MLD" SRL, has successfully completed H30 pro, H60 series training courses including operation and maintenance, and is qualified to offer technical support for above mentioned products.

深圳市理邦精密仪器股份有限公司
EDAN INSTRUMENTS, INC.

赖晓宇

International Customer Service Manager

Date Nov 1st, 2023