



Product Service

Certificate

No. Q5 091264 0016 Rev. 05

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, Video Colposcope, Ultrasonic Transducer, TOCO Transducer, SPO2 Sensor, Temperature Probe, ECG Cable, Telemetry Transmitter, NIBP Cuff, 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, Blood Pressure Monitor, Fetal & Maternal Module, Telemetry Monitor, Mobile Cardiac Telemetry, In Vitro Diagnostic Reagent or Reagent Kits, In Vitro Diagnostic Instrument and related Consumables for Clinical Chemistry, Immunochemistry (Immunology), Haematology.

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, 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:Q5_091264_0016_Rev.05

Report No.: BJ25089101

Valid from: 2025-12-01
Valid until: 2028-11-30

Date, 2025-09-26

Christoph Dicks
 Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

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