





Certificate

No. Q5 091264 0016 Rev. 00

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); 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. Anaesthetic Workstation, Ventilator, Specific Protein Immunoassay System (including Wide-Range C-Reactive Protein Assay kit, Assay buffer, Sample dilution buffer, Washing buffer, Protein Analyzer)

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). See also notes overleaf.

Report No.: BJ17891026_BJ1889103

 Valid from:
 2018-10-29

 Valid until:
 2019-11-30

Date, 2018-10-29

Stefan Preiß

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EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Edan Instruments, Inc.

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Pingshan District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF

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