



America

CERTIFICATE

No. QS5 091264 0017 Rev. 00

Certificate Holder:

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:

See Page 2 for Overall Scope Statement.

Standard(s):

ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

BJ17891026_BJ1889103

Effective Date:

2018-09-13

Expiry Date:

2021-09-12

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Date of Issue: 2019-02-05

Ally

(Arie Henkin)
Manager, Certification Body MHS

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TÜV®



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No. QS5 091264 0017 Rev. 00

Overall Scope Statement:

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, PC ECG, STRESS ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Data Management Software, Trolley (for Medical Use), Veterinary Electrocardiograph, 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); Veterinary PC ECG, Veterinary Pulse Oximeter, Veterinary Digital Ultrasonic Diagnostic Imaging System, Veterinary Monitor, Veterinary Diagnostic Ultrasound System, Veterinary Blood Gas and Chemistry Analysis System (including Veterinary Blood Gas and Chemistry Analyzer, Veterinary Calibrant Fluid Pack, Veterinary Test Cartridge)

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