N3 UL- 16 12 120



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 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), Veterinary Electrocardiograph, 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, Veterinary Controls), Veterinary Hematology Analyzer, Reagents for Veterinary Hematology Analyzer (including Veterinary Diluent, Veterinary Lyse, Veterinary Cleaner), Biofeedback and Stimulation System, EMG/Stimulation Sensor, Ambulatory Blood Pressure Monitor, NIBP Tube, Connection Cable, Needle Guide Bracket, ECG Analysis software, Fetal Telemetry System, Electrosurgical Generator, Battery.

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 2021-09-13 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 (<u>www.cnca.gov.cn</u>).

Head of Certification Body Munich, 2021-07-12

