



Product Service

CERTIFICATE

No. Q1N 17 05 91264 008

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, Ultrasound Scanner, 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), 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; Video Colposcope; Ultrasonic Transducer, TOCO Transducer; SPO2 Sensor; Temperature Probe; ECG Cable, Telemetry Transmitter, NIBP Cuff, Anaesthetic Workstation, Ventilator.

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.: BJ17891021**Valid from:** 2017-08-22**Valid until:** 2019-11-30**Date,** 2017-08-22

Stefan Preiß



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CERTIFICATE**No. Q1N 17 05 91264 008****Applied Standard(s):**

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

Facility(ies):

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan
District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

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