



America

CERTIFICATE

No. QS1 13 12 44180 026

Certificate Holder: Edan Instruments, Inc.
 3/F-B, Nanshan Medical Equipments Park
 Nanhai Rd. 1019#, Shekou
 Nanshan District
 518067 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, Ultrasonic Pocket Doppler, Patient Monitor, Electrocardiograph, Ultrasound Scanner, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, PC ECG, STRESS ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, 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); Hematology Analyzer; Reagents for Hematology Analyzer; Video Colposcope; Ultrasonic Transducer, TOCO Transducer SPO2 Sensor; Temperature Probe; ECG Cable

Standard(s): ISO 13485:2003

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.

TÜV SÜD America Inc. is a Health Canada CMDCAS Recognized Registrar.

Report No.: M4392
Effective Date: 2013-12-03
Expiry Date: 2016-12-02

Gary Minks
 Vice President, Regulatory Affairs

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TÜV SÜD America Inc.
 10 Centennial Drive
 Peabody, MA 01960
 USA

TÜV®





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Edan Instruments, Inc.
3/F-B, Nanshan Medical Equipments Park
Nanhai Rd. 1019#, Shekou
Nanshan District
518067 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Design and Development, and Distribution of Transcranial Doppler System, Fetal Monitor, Fetal & Maternal Monitor, Ultrasonic Pocket Doppler, Patient Monitor, Electrocardiograph, Ultrasound Scanner, Central Monitoring System, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, PC ECG, STRESS ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Trolley (for medical use), Veterinary Electrocardiograph, ECG Electrode, Holter System, Treadmill (for medical use), Diagnostic Ultrasound System, Ultrasonic Imaging Management System, Blood Gas Chemistry Analysis System(including Blood Gas Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge); Hematology analyzer; Reagents for hematology analyzer; Video Colposcope; Ultrasonic Transducer, TOCO Transducer; SPO2 Sensor; Temperature Probe; ECG Cable.

Edan Instruments, Inc.
2/F and 5/F, block A/B
Unit 8, Xing Hua Building
Nanhai Rd., Nanshan
(6th Industrial Road, Shekou)
518067 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Production of Transcranial Doppler System, Fetal Monitor, Fetal & Maternal Monitor, Ultrasonic Pocket Doppler, Patient Monitor, Electrocardiograph, Ultrasound Scanner, Central Monitoring System, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, PC ECG, STRESS ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Trolley (for medical use), Veterinary Electrocardiograph, ECG Electrode, Holter System, Treadmill (for medical use), Diagnostic Ultrasound System, Ultrasonic Imaging Management System, Blood Gas Chemistry Analysis System(including Blood Gas Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge); Hematology analyzer; Reagents for hematology analyzer; Video Colposcope; Ultrasonic Transducer, TOCO Transducer; SPO2 Sensor; Temperature Probe; ECG Cable.

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Vice President, Regulatory Affairs



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No. QS1 13 12 44180 026

Edan Instruments, Inc.
A301-310,Nanshan Medical Equipments Park
Nanhai Rd 1019#, Shekou, Nanshan
518067 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Design and Development, and Production of Transcranial Doppler System, Fetal Monitor, Fetal & Maternal Monitor, Ultrasonic Pocket Doppler, Patient Monitor, Electrocardiograph, Ultrasound Scanner, Central Monitoring System, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, PC ECG, STRESS ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Trolley (for medical use), Veterinary Electrocardiograph, ECG Electrode, Holter System, Treadmill (for medical use), Diagnostic Ultrasound System, Ultrasonic Imaging Management System, Blood Gas Chemistry Analysis System(including Blood Gas Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge); Hematology analyzer; Reagents for hematology analyzer; Video Colposcope; Ultrasonic Transducer, TOCO Transducer; SPO2 Sensor; Temperature Probe; ECG Cable.

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