



EC Certificate

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 091264 0006 Rev. 02

Manufacturer: Edan Instruments, Inc.

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District

Pingshan District 518122 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Edan Instruments, Inc. Facility(ies):

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF

CHINA

Product Category(ies): Fetal Monitor, Fetal & Maternal Monitor, Ultrasonic

Pocket Doppler, Patient Monitor.

Electrocardiograph, Central Monitoring System, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, PC ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler. Diagnostic Ultrasound System, Holter System, Telemetry Transmitter, Anaesthetic Workstation. Ventilator, Biofeedback and Stimulation System. **Ambulatory Blood Pressure Monitor, SPO2 Sensor:**

Temperature Probe; Ultrasonic Transducer.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

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Valid from: 2019-11-25 Valid until: 2022-09-17

2019-11-25 Date.

Christoph Dicks

Head of Certification/Notified Body

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