



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. 03

Manufacturer:

Edan Instruments, Inc.

#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, 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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10912640006Rev.03

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Christoph Dicks
Head of Certification/Notified Body