



Product Service

# 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 17 05 91264 006

**Manufacturer:****Edan Instruments, Inc.**

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

**EC-Representative:****Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80  
20537 Hamburg  
GERMANY

**Product Category(ies):**

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, STRESS ECG, PC ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Diagnostic Ultrasound System, Holter System, Telemetry Transmitter, Anaesthetic Workstation, Ventilator.

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.

**Report No.:**

BJ1789107

**Valid from:**

2017-09-18

**Valid until:**

2022-09-17

**Date,** 2017-08-31

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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Shekou, Nanshan District, 518067 Shenzhen, PEOPLE'S  
REPUBLIC OF CHINA