



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 12 12 44180 028

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

3/F-B, Nanshan Medical Equipments Park  
Nanhai Rd. 1019#, Shekou  
Nanshan District  
518067 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.

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.:**

BJ1289104-3

**Valid from:**

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**Valid until:**

2017-09-17



Hans-Heiner Junker

**Date,** 2013-06-06

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

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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

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2/F and 5/F, block A/B, Unit 8, Xing Hua Building, Nanhai Rd.,  
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PEOPLE'S REPUBLIC OF CHINA

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