



Product Service

EC - CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 07 08 44180 008

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, Patient Monitor, Central Monitoring System, Ultrasound Scanner, Ultrasonic Pocket Doppler, Electrocardiograph**

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 products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: BJ789101

Valid until: 2012-09-17

Date, 2007-09-19


 Reiner Krumme



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.



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EC-Certificate

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 07 08 44180 008

Facility(ies):

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



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

EDAN Instruments, Inc.

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

has established and applies
a Quality Management System for

**Design and Development, Production and Distribution of Transcranial
Doppler System, Fetal Monitor, Fetal & Maternal Monitor, Patient
Monitor, Central Monitoring System, Ultrasound Scanner, Ultrasonic
Pocket Doppler, Electrocardiograph, Pulse Oximeter, Digital Ultrasonic
Diagnostic Imaging System, PC ECG**

An audit was performed, Report No. **70083559**

Proof has been furnished that the requirements
according to

ISO 9001: 2000

are fulfilled. The certificate is valid until **2010-11-30**

Certificate Registration No. **12 100 25284 TMS**



Munich, 2008-01-08



QMS-TGA-ZM-07-92



Product Service

CERTIFICATE

No. Q1N 07 12 44180 010

Holder of Certificate: **Edan Instruments, Inc.**

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

Facility(ies):

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, Patient Monitor, Central Monitoring System, Ultrasound Scanner, Ultrasonic Pocket Doppler, Electrocardiograph, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, PC ECG

Applied Standard(s):

ISO 13485:2003
Medical Devices – Quality Management Systems – Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

BJ789104

Valid until:

2010-11-30

Date, 2008-01-04

Reiner Krumme



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