ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 07 44180 024

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.: BJ1289107

Valid from: 2012-09-18
Valid until: 2017-09-17

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Date, 2012-09-10

Hans-Heiner Junker

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

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Facility(ies):

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

Edan Instruments, Inc.
2/F and 5/F, block A/B, Unit 8, Xing Hua Building, Nanhai Rd.,
Nanshan, (6th Industrial Road, Shekou), 518067 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

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