



Product Service

TÜV SÜD Product Service GmbH • Ridlerstraße 65 • 80339 Munich • Germany

Choose certainty.  
Add value.

## To Whom It May Concern

Munich, 2012-11-05

### Confirmation concerning certificates

We confirm that the following certificates:

**G1 12 07 44180 024** (valid until 2017-09-17)

**G2 10 09 44180 023** (valid until 2015-03-18)

issued to the following auditee

**Edan Instruments, Inc.**  
**3/F-B, Nanshan Medical Equipments Park**  
**Nanhai Rd. 1019#, Shekou**  
**Nanshan District, 518067Shenzhen**  
**P.R.China**

covering the Directive 93/42/EEC on Medical Devices with the scope:

scope of the certificate G1 12 07 44180 024:

**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**

and the following products:

No.	Product	Model
1	Fetal Monitor	Cadence
		Cadence Pro
		Cadence Dual
		Cadence II



		F2
		F3
2	Ultrasonic Pocket Doppler	Sonotrax Lite
		Sonotrax Basic
		Sonotrax Pro
		Sonotrax Vascular
		Sonotrax Basic A
		Sonotrax II
		Sonotrax II Pro
3	Patient Monitor	M9
		M9A
		M9B
		iM9
		iM9A
		M8
		M8A
		M8B
		iM8
		iM8A
		iM8B
		M80
		M50
		iM80
		iM50
		elite V8
		Vista 120
4	Electrocardiograph	SE-1
		SE-100
		SE-3
		SE-300A
		SE-300B
		SE-6
		SE-12
		SE-12 Express
		SE-601A
		SE-601B
		plusMED pmECG-601B



		SE-601C
		pmECG-100
		pmECG-300A
		pmECG-300B
		pmECG-600
		pmECG-1200
		pmECG-1200 Express
		SE-600
		SE-1200
		SE-1200 Express
		SE-1201
5	Ultrasound Scanner	SONOFINE EUS L
		SONOFINE EUS B
		SONOFINE EUS B2
		SONOFINE EUS B2 PLUS
		SONOFINE EUS T
6	Transcranial Doppler System	CBS-USB Module
		CBS-USB
7	Central Monitoring System	MFM-CNS
		MFM-CMS
8	Fetal & Maternal Monitor	F9
		F9 Express
		F6
		F6 Express
9	Digital Ultrasonic Diagnostic Imaging System	DUS 3
		DUS 6
		DUS 8
		D3
		D6
		DUS 60
10	Pulse Oximeter	H100B
		PM-100B
		H100N
11	PC ECG	SE-1010
12	STRESS ECG	ST-1212
13	Vital Signs Monitor	M3
		M3A



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		M3B
		Plus-3A
14	Finger Oximeter	H10
15	Ultrasonic TableTop Doppler	SD5
		SD6
		Plus-6
16	Diagnostic Ultrasound System	U50
		U2

scope of the certificate Certificate G2 10 09 44180 023:

**Holter System**

and the following products:

No.	Product	Model
1	Holter System	SE-2003
		SE-2012

With this letter, TÜV SÜD Product Service GmbH confirms that the above products are certified and permitted to be labelled with the CE Mark and may be marketed in the European Union.

  
 i.A. Hermann Fürgut  
 TÜV SÜD PRODUCT SERVICE GMBH  
 Medical Health Services  
 Foreign Affairs

