



Product Service

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

## To Whom It May Concern

**Choose certainty.  
Add value.**

München, 2017-11-09

### Confirmation concerning certificates

We confirm the following certificates:

**G1 17 05 91264 006** (valid until 2022-09-17)

**G2 17 06 91264 009** (valid until 2020-07-02)

issued to the legal medical device manufacturer

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

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

scope of the certificate **G1 17 05 91264 006**:

**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.**

and the following products:

No.	Product	Model
1	Fetal Monitor	F2
		F3
2	Ultrasonic Pocket Doppler	Sonotrax Lite

Trade Register Munich HRB 85742  
HypoVereinsbank Munich  
Acc. No. 48 852 211  
Bank Code 700 202 70  
VAT ID No. DE129484267  
Information pursuant to Section 2(1)  
DL-InfoV (Germany)  
at [www.tuev-sued.com/imprint](http://www.tuev-sued.com/imprint)

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**TÜV**<sup>®</sup>

TÜV SÜD Product Service GmbH  
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Ridlerstraße 65  
80339 Munich  
Germany



		Sonotrax Basic
		Sonotrax Pro
		Sonotrax Vascular
		Sonotrax Basic A
		Sonotrax II
		Sonotrax II Pro
		SD3 LITE
		SD3
		SD3 PLUS
		SD3 PRO
		SD3 VASCULAR
		SD1
3	Patient Monitor	M9
		M9A
		M8
		M8A
		M8B
		M50
		M80
		Vista 120
		Vista 120 S
		elite V5
		elite V6
		elite V8
		iM9
		iM9A
		iM8
		iM8A
		iM8B
		iM50
		iM60
		iM70



		iM80
		iM20
		iM3
4	Electrocardiograph	SE-1
		SE-100
		SE-3
		SE-300A
		SE-300B
		SE-12
		SE-12 Express
		SE-1200
		SE-1200 Express
		SE-1201
		CS-1201
		SE-601A
		SE-601B
		SE-601C
		CS-601B
		CS-601C
		SE-15
		SE-18
		SE-301
		iSE-301
5	Central Monitoring System	MFM-CNS
		MFM-CNS Lite
		MFM-CMS
		Vista 120 CMS
		FTS-6
6	Fetal & Maternal Monitor	F9
		F9 Express
		F6
		F6 Express



7	Digital Ultrasonic Diagnostic Imaging System	DUS 60
8	Pulse Oximeter	H100B
		PM-100B
		H100N
09	PC ECG	SE-1010
		PADECG
		SE-1515
10	Vital Signs Monitor	M3
		M3A
		M3B
		Plus-3A
11	Finger Oximeter	H10
12	Ultrasonic TableTop Doppler	SD5
		SD6
13	Diagnostic Ultrasound System	U50
		U2
		Acclarix AX8
		Acclarix LX8
		Acclarix AX4
14	Telemetry Transmitter	iT20
15	Holter System	SE-2003
		SE-2012
16	Anaesthetic Workstation	Long5
		Long8
17	Ventilator	VT5

scope of the certificate **G2 17 06 91264 009**:

**Holter System.**



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and the following products:

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

With this letter we confirm that the above mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the Notified Body TÜV SÜD Product Service GmbH.

*R. Köhler*



i.A. Randolph Köhler  
TÜV SÜD PRODUCT SERVICE GMBH  
Medical Health Services  
Foreign Affairs