



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 that the following certificates:

Q1N 17 05 91264 008 (valid until 2019-11-30)

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**

covers a quality system according to EN ISO 13485:2012+AC:2012 and ISO13485:2003 with the scope:

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, STRESS ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Data Management Software, Trolley (for medical use), ECG Electrode, Holter System, Treadmill (for medical use), Diagnostic Ultrasound System, Ultrasonic Imaging Management System, Blood Gas and Chemistry Analysis System (including Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge, Controls); Hematology analyzer; Reagents for hematology analyzer; Video Colposcope; Ultrasonic Transducer, TOCO Transducer; SPO2 Sensor; Temperature Probe; ECG Cable, Telemetry Transmitter, NIBP Cuff, Anaesthetic Workstation, Ventilator.

and the following products:

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

Supervisory Board:
Dirk Eilers (Chairman)
Board of Management:
Robert Kees (CEO)
Dr. Jens Butenandt
Holger Lindner

Phone: +49 89 5008-40
Fax: +49 89 5008-4222

www.tuev-sued.de
TÜV®

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



No.	Product	Model
1	Fetal Monitor	F2
		F3
2	Ultrasonic Pocket Doppler	Sonotrax Lite
		Sonotrax Basic
		Sonotrax Pro
		Sonotrax Vascular
		Sonotrax Basic A
		Sonotrax II
		Sonotrax II Pro
		SD3 LITE
		SD3
		SD3 PLUS
		SD3 PRO
		SD3 VASCULAR
3	Patient Monitor	SD1
		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
9	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



Product Service

14	Telemetry Transmitter	iT20
15	Holter System	SE-2003
		SE-2012
16	Video Colposcope	C3, C6, C6 HD, C600, iHC6 C3A, C6A, C6A HD, C300A, iHC3A
17	Blood Gas and Chemistry Analyzer	i15
18	Calibrant Fluid Pack	CP50, CP100
19	Test Cartridge	BG8, BG3, BC4, BG4, BG9, BG10, BG5, BG6
20	Controls	Level 1, Level 2, Level 3
21	Hematology analyzer	DS500, DS500i
22	Reagents for hematology analyzer (for DS500, DS500i)	HD-50 cleaner HD-50 lyse HD-50 diluent
23	Hematology analyzer	H30
24	Reagents for hematology analyzer (for H30)	HD300 Diluent HL300 Lyse HC300 Cleaner HB300 Bleach
25	Anaesthetic Workstation	Long5
		Long8
26	Ventilator	VT5

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

