Product Service

Add value.
Inspire trust.

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

To whom it might concern

Munich, 2020-04-02
Order No.: 713184641

Confirmation concerning EC Certificate G1 091264 0006 Rev. 02

We confirm that the following certificate:

G1 091264 0006 Rev. 02 (valid until 2022-09-17)

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

Fetal Monitor, Fetal & Maternal Monitor, Ultrasonic Pocket Doppler, Patient Monitor, Electrocardiograph, Central Monitoring System, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, PC ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Diagnostic Ultrasound System, Holter System, Telemetry Transmitter, Anaesthetic Workstation, Ventilator, Biofeedback and Stimulation System, Ambulatory Blood Pressure Monitor, SPO2 Sensor; Temperature Probe; Ultrasonic Transducer.

and the following devices:

Name of Product	Models
Fetal Monitor	F2
	F3
	FTS-6 Mobile
Fetal & Maternal Monitor	F9
	F9 Express
	F6
	F6 Express
	F15
	F15 Air

Product Service

Name of Product	Models
Patient Monitor	M8
	M8A
	M8B
	M50
	M80
	Vista 120
	Vista 120 S
	iM8
	iM8A
	iM8B
	iM50
	iM80
	iM60
	iM70
	iM20
	elite V5
	elite V6
	elite V8
	X8
	X10
	X12
Central Monitoring System	MFM-CNS
	MFM-CNS Lite
	MFM-CMS
	Vista 120 CMS
	FTS-6
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
	SD1
Electrocardiograph	SE-1
	SE-100
	SE-3
	SE-300A
	SE-300B
	SE-12
	SE-12 Express
	SE-1200
	SE-1200 Express
	SE-1201

Product Service

Name of Product	Models
	CS-1201
	SL12A
	SE-601A
	SE-601B
	SE-601C
	CS-601B
	CS-601C
	SL6A
	SE-15
	SE-18
	SL18A
	SE-301
	iSE-301
Pulse Oximeter	H100B
	PM-100B
	H100N
Digital Ultrasonic Diagnostic Imaging System	DUS 60
PC ECG	PADECG
	SE-1515
Vital Signs Monitor	M3
	M3A
	M3B
	iM3
	Vista 120SC
Finger Oximeter	H10
Ultrasonic TableTop Doppler	SD5
	SD6
Holter System	SE-2003
	SE-2012
Diagnostic Ultrasound System	U50
	U2
	Acclarix AX8
	Acclarix LX8
	Acclarix AX4
	Acclarix LX4
	U60
	Acclarix AX3
	Acclarix AX3 Exp
	Acclarix AX3 Super
	Acclarix AX25
	Acclarix AX28
	Acclarix AX2
	Acclarix AX2 Exp
	Acclarix AX2 Super
	Acclarix AX15
	Acclarix AX18
	Acclarix LX9
	Acclarix LX9 Exp

Product Service

Name of Product	Models
	Acclarix LX9 Super
	Acclarix LX85
	Acclarix LX88
Telemetry Transmitter	iT20
Anaesthetic workstation	Long5;
	Long8
Ventilator	VT 5
	VT 2
Biofeedback and Stimulation System	P4
	P E 4
	P4 Plus
	P4 Pro
	P36
	P2
	P16
	PE2
	PE16
Ambulatory Blood Pressure Monitor	SA-05
	SA-06
	SA-08
	SA-09
	SA-10
SPO2 sensor	02.57.225029,02.01.210119, 02.01.210120,02.01.210673, 02.01.210121,02.01.210122, 02.57.225000,01.57.471235, 01.57.471236,01.57.471237, 01.57.471238,01.57.471746, 01.57.471747,01.57.471748, 01.57.471749,
Temperature Probe	01.15.040226,01.15.040253, 01.15.040225,01.15.040255, 01.15.040227,01.15.040254, 01.15.040228,01.15.040256, 01.15.040257,01.15.040422, 01.15.040258,01.15.040423, 01.15.040185,01.15.040420, 01.15.040184,01.15.040421, 01.15.040188,01.15.040424
ultrasonic transducer	C5-2Q, L12-5Q, E8-4Q, L17-7Q, P5-1Q, C5-2XQ, L10-4Q, P5-1XQ, L17-7HQ, L17-7SQ, C5-2MQ, MC8-4Q, P7-3Q, MC9-3TQ, C7-2XQ, C5-2XD, L10-4D, P5-1XD, L17-7HD, L17-7SD, C5-2MD, C5-2D, MC8-4D, L12-5D, P5-1D, MC9-3TD, P7-3D, E8-4D, C7-2XD, C352UB, L742UB, E612UB, L1042UB, C612UB, C6152UB, C422UB, L552UB, C5-2b, L15-7b, P5-1b, C361-2, C611-2, E611-2, L743-2, L761-2, E741-2

Product Service

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.

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

The above-mentioned certificate is valid.

R. Köhler

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