

# EDANUSA

www.edanusa.com

# H100B

## Handheld Pulse Oximeter

As a handheld pulse oximeter, H100B is designed to serve the needs of both long-term monitoring and spot check. It's dedicated to offer reliable, accurate and sensitive measurement of blood oxygen saturation under even harsh conditions.

**Measured Parameters: SpO<sub>2</sub>+PR**

**300 h**

SpO<sub>2</sub> Review

**100**

Patient ID



Care for Health

# H100B

## Handheld Pulse Oximeter

### Mounting Solutions



Bed Rail Mount



Carrying Bag



Charger Stand

- LCD display with backlight control
- Dual work modes: monitoring & spot check
- Numeric display with plethysmogram display
- Trend review
- Pulse-tone modulation (Pitch Tone)
- Adjustable audio and visual alarms
- Powerful data storage capacity (up to 300 hours)
- PatientCare Viewer software for PC data management
- 4 x AA batteries for up to 48 hours of work
- Rechargeable battery for up to 30 hours of work
- Optional battery charger stand
- Automatic power-off function for power saving

## Specification

### Classification

Type of Protection	Internally power equipment (on battery power)
EMC Compliance	Class B
Degree of Protection	Type BF-Applied Part
Mode of Operation	Continuous
Enclosure Degree of Ingress Protection	IPX2

### Size and Weight

Size	160 (L)x70 (W)x37.6 (H) (mm)
Weight	165 g (without batteries)

### Environment

Temperature	
Working	5 C~40 C
Storage/Shipping	-20 C~55 C
Humidity	
Working	25%~80% (Non-condensing)
Storage/Shipping	25%~93% (Non-condensing)

### Display

H100B	LCD (128*64)
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### Charger Stand

Input Voltage	100 to 240V AC, 50/60 Hz
Output Voltage	6 V DC
Output Current	0.8 A
Output Power	6.4 W

### Battery

#### Ni-MH Rechargeable Battery Package

Quantity	1
Total Rated Voltage	4.8 V
Capacity	1800 mAh
Typical Battery Life	30 hours
Charge Time	2.5 hours to 80% 4 hours to 100%

Alkaline Batteries	
Typical Battery Life	4 pieces 1.5 V AA 48 hours

### Measuring Parameter Specification

Measurement Range	
SpO2	0-100%
PR	25-300 bpm
SpO2 Accuracy	
Adult (Pediatric)	+2% (70%-100%)
Neonate	+3% (70%-100%)
Pulse Rate Accuracy	
Adult/Pediatric	+3 bpm
Neonate	+3 bpm
SpO2 Resolution	1%
PR Resolution	1 bpm



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für Gesundheitsschutz  
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Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



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 091264 0006 Rev. 02**

## Manufacturer:

**Edan Instruments, Inc.**

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

## Facility(ies):

Edan Instruments, Inc.

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

**Product Category(ies):** 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.

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.:**

BJ1989104

**Valid from:**

2019-11-25

**Valid until:**

2022-09-17

**Date,**

2019-11-25

Christoph Dicks  
Head of Certification/Notified Body



America

# CERTIFICATE

No. QS5 091264 0017 Rev. 00

Certificate Holder:

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

Certification Mark:



Scope of Certificate:

See Page 2 for Overall Scope Statement.

Standard(s):

ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

BJ17891026\_BJ1889103

Effective Date:

2018-09-13

Expiry Date:

2021-09-12

Page 1 of 2

Date of Issue: 2019-02-05

( Arie Henkin )  
Manager, Certification Body MHS

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TUV®





# CERTIFICATE

No. QS5 091264 0017 Rev. 00

## Overall Scope Statement:

Design and Development, Production and Distribution of Transcranial Doppler System, Fetal Monitor, Fetal & Maternal Monitor, Patient Monitor, Central Monitoring System, 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), Veterinary Electrocardiograph, 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 (including Diluent, Lyse, Cleaner, Bleach, Hematology Control, Hematology Calibrator); Video Colposcope; Ultrasonic Transducer, TOCO Transducer; SPO2 Sensor; Temperature Probe; ECG Cable; Telemetry Transmitter, NIBP Cuff, Anaesthetic Workstation, Ventilator; Specific Protein Immunoassay System (including Wide-Range C-Reactive Protein Assay Kit, Assay Buffer, Sample Dilution Buffer, Washing Buffer, Protein Analyzer); Veterinary PC ECG, Veterinary Pulse Oximeter, Veterinary Digital Ultrasonic Diagnostic Imaging System, Veterinary Monitor, Veterinary Diagnostic Ultrasound System, Veterinary Blood Gas and Chemistry Analysis System (including Veterinary Blood Gas and Chemistry Analyzer, Veterinary Calibrant Fluid Pack, Veterinary Test Cartridge)

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Date of Issue: 2019-02-05

( Arie Henkin )  
Manager, Certification Body MHS

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TÜV®



Product Service

# Certificate

No. Q5 091264 0016 Rev. 01

**Holder of Certificate:** **Edan Instruments, Inc.**

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

**Certification Mark:**



**Scope of Certificate:**

Design and Development, Production and Distribution of Transcranial Doppler System, Fetal Monitor, Fetal & Maternal Monitor, Patient Monitor, Central Monitoring System, Ultrasonic Pocket Doppler, Electrocardiograph, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, STRESS ECG, PC 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, External electronic simulator, capillary adaptor, Ampoule adaptor); Hematology analyzer; Reagents for Hematology Analyzer (including diluent, lyse, cleaner, bleach, hematology control, hematology calibrator); Video Colposcope; Ultrasonic Transducer, TOCO Transducer; SPO2 Sensor; Temperature Probe; ECG Cable, Telemetry Transmitter, NIBP Cuff, Anaesthetic Workstation, Ventilator, Specific Protein Immunoassay System (including Protein Assay kit, Assay buffer, Sample dilution buffer, Washing buffer, Protein Analyzer), Biofeedback and Stimulation System, EMG/ Stimulation sensor, Ambulatory Blood Pressure Monitor, Medical Air Compressor, NIBP Tube, Connection Cable, Water Trap, Needle Guide Bracket.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the

# Certificate

No. Q5 091264 0016 Rev. 01

requirements of the listed standard(s). See also notes overleaf.

**Report No.:** BJ1989104

**Valid from:** 2019-12-01

**Valid until:** 2022-11-30

**Date,** 2019-11-25



Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 091264 0016 Rev. 01

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

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