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# iE 300

## Technical Specifications

## Signal processing specification:

ECG interpretation	Biocare CardioPro ECG analysis program for adults and pediatrics
Acquisition mode	Simultaneous standard 12-lead acquisition
A/D conversion	24 bit
Sampling rate	8,000 samples/s
Frequency response	0.05 Hz ~ 250 Hz
Signal measurement range	-5mV ~ +5mV
Common mode rejection ratio	>115dB
Polarization voltage	$\pm 500$ mV
Input circuit	Floating circuit input
Input impedance	$\geq 50$ M $\Omega$
Input CIR current	$\leq 0.1$ $\mu$ A
Patient leakage current	<10 $\mu$ A
Time constant	$\geq 3.2$ s
Noise level	$\leq 12.5$ $\mu$ V <sub>p-p</sub>
Sensitivity threshold	$\leq 20$ $\mu$ V
Calibration voltage	1 mV $\pm 3$ %
Sensitivity	(0.625, 1.25, 2.5, 5, 10, 20, 40, 10/5, 20/10) mm/mV, Auto Gain
Filter setting	EMG filter: 25/35/75/100/150/250Hz Baseline wander filter: 0.01/0.02/0.05/0.35/0.5/0.8Hz
AC filter	50Hz, 60Hz
Heart rate range	30~300 bpm
Special acquisition functions	Lead-off detection, lead overflow, AC interference, baseline wander interference, EMG interference
Acquisition time	10~24 seconds

**Display and keyboard specifications:**

Display type	5 inch TFT LCD
Display resolution	800×480
Display data	Waveforms, heart rate, clock, printing mode, filters, sensitivity, paper speed, system prompt, alarming messages, battery, power indicator, tone level
Waveform display mode	1) Same screen display: 3*4, 3*4+1R, 6*2, 6*2+1R, 12*1 2) Split-screen display: 3*4 , 3*4+1R
Keyboard type	Silicon quick-access function keys

**Recorder specifications:**

Recorder technology	Thermal dot matrix word printing system
Recorder resolution	8 points/mm (perpendicular) 40 points/mm (horizontal, 25 mm/s)
Recorder speed	(5, 6.25, 10, 12.5, 25, 50) mm/s±5 %
Recording paper	80 mm, roll paper

**Standard software specifications:**

Measurement and interpretation	Supports measurement and interpretation with Biocare CardioPro ECG analysis program for adults and pediatrics
Measurement values	HR, PR interval, QRS duration, QT/QTc interval, P/QRS/T axis, RV5/SV1 amplitude, RV5+SV1

	amplitude
Minnesota code	With newest Minnesota code
Working mode	Automatic mode, Manual mode, Rhythm mode, Upload mode
DEMO mode	Normal ECG, Arrhythmia ECG
QTC formula	Bazett, Fridercia, Framingham, Hodges
Rhythm analysis	Single rhythm mode: 30-300 seconds
Extended printing in arrhythmia	Supports extended arrhythmia waveform printing in automatic mode
Waveform frozen	Supports 300 seconds of waveform frozen
Pacemaker detection	Weak, Normal, Enhance
Report auto-saved	Selectable auto-saved file
Interpretation printout	Selectable interpretation printing
Report preview	Preview the report before printing
Data format	ECG, DICOM, XML, JPEG, PDF
Patient information setting	Record No., Name, Gender, D.O.B, Height, Weight, BP, Race, Pacemaker, Medication, Accession No., Ref-physician, Technician, Physician, Room No., User-define
Language	Chinese, English, Spanish, Portuguese, Russian, Polish, German, Czech, French, Italian, Ukrainian, Turkish
Local memory capacity	More than 3000 files

## Report specifications:

Report type	Manual report, Simple report, MVB report(Median beat report)
Record format	3*4, 3*4+1R; 1*12, 1*12+1R; 3/2

## External peripheral use:

Patient cable socket	Connect to the patient cable
Two USB port	Support USB flash disk and barcode scanner
LAN port	Communication with ECG-1000 workstation software on PC

## Power supply

Power supply	AC / DC
AC power supply	100 V~240 V, 50 Hz /60 Hz, 80 VA
Battery power supply	Rechargeable lithium battery, 11.1V, 2600mAh
Battery capacity	Supports about 3 hours for continuous operation, no less than 350 pcs 3 channels ECG exams and reports recording
Battery charge time	Approximately 4 hours for total charge

## Dimensions and weight

Length × width × height	281 mm×191 mm×59 mm
Weight:	About 1.3 kg

## Standard accessories

ECG Cable	10 lead wires,TPU, banana plug, defi, IEC
Chest Electrode	Adult chest electrode,Φ4mm,6pcs/set
Limb Electrode	Adult limb electrode, Φ4mm, 4pcs/set, no

	LOGO, light blue color
Thermal Recording Paper	Roll paper,80mmx20m,no LOGO
Paper roller	ABS fire-proof UL94V-0
Power Cord	L=1900±100mm H05VV-F/3G*0.75 AP24/AC24, black, European standard
Grounding Cable	L=4mm UL1015 14AWG
Battery	HYLB-1994,11.1V 2600mAh

## Environment requirements

1	Transportation	
	Environment temperature	-20°C~+55 °C
	Relative humidity	≤95% (No condensation)
	Air pressure	70 kPa~106 kPa
	In accordance with the requirements stipulated in the contract order, the transport process to prevent rain and sun.	
2	Storage	
	Environment temperature	-20°C~+55°C
	Relative humidity:	≤95%(No condensation)
	Air pressure	70 kPa~106 kPa
	The packaging of ECG stored in the non-corrosive gases and well-ventilated room.	
3	Using	
	Environment temperature	+5 °C~+40
	Relative humidity:	≤95%(No condensation)
	Air pressure	86 kPa~106 kPa

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- Based on the need of product technical improvement or the file updates, we reserve the right to modify the contents contained in this manual; if the change does not involve safety issues, the contents are subject to amend without notification

**Mobile Trolley for ECG**  
**Suitable for BIOCARE ECG**  
(Model: IV-Cart)

**Features**

- Easy, flexible height, rotation, tilting adjustment
- Elegant Integrated design, quick installation, fine workmanship
- Excellent durable, environmentally friendly material, with high resistance to corrosion
- basket for accessories / consumables placement
- Stable and easy-moving 4 universal wheels of 2 with braker
- Aluminum alloy tray with rail for flexible support of different models

**Specifications**

Size: 46cm x 58cm x H (65 to 120cm adjustable)

Weight: 10kg

Max. Load: 25kg

Wheel diameter: 50mm



**Shenzhen Biocare Bio-Medical Equipment Co., Ltd.**

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## DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



*SHENZHEN BIOCARE BIO-MEDICAL EQUIPMENT CO., LTD.*  
*#16-1, JINHUI ROAD, JINSHA COMMUNITY, KENGZI SUB-DISTRICT, PINGSHAN NEW DISTRICT, 518122*  
*SHENZHEN, PEOPLE'S REPUBLIC OF CHINA*

MEDICAL DEVICE: *DIGITAL ELECTROCARDIOGRAPH*  
*TYPE: iE 101, iE 300*  
*GMDN CODE: 16231*

CLASSIFICATION - ANNEX IX: *CLASS IIA, RULE 10*

CONFORMITY ASSESSMENT ROUTE: *ANNEX II EXCLUDING(4)*

**WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES  
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE  
93/42/EEC CONCERNING MEDICAL DEVICES;  
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.  
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.  
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.**

NOTIFIED BODY: **TÜV SÜD PRODUCT SERVICE GMBH**  
**Ridlerstraße 65 · 80339 Munich · Germany**

IDENTIFICATION NUMBER

**CE** 0123

(EC) CERTIFICATE(S): *G1 065758 0004 REV.01*



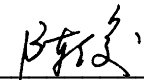
EUROPEAN REPRESENTATIVE:

*SHANGHAI INTERNATIONAL HOLDING CORP. GMBH*  
*(EUROPE)*  
*Eiffestraße 80, 20537 Hamburg, GERMANY*

START OF CE-MARKING: *2017-05-20*

PLACE, DATE OF DECLARATION: *SHENZHEN P.R.C., 2019-09-19*

SIGNATURE:

  
NAME: CHENJUN  
POSITION: GENERAL MANAGER





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Zentralstelle der Länder  
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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 065758 0004 Rev. 01**

## Manufacturer:

**Shenzhen Biocare Bio-Medical  
Equipment Co., Ltd.**

#16-1 Jinhui Road, Jinsha Community, Kengzi Sub-District,  
Pingshan New District  
518122 Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

## Facility(ies):

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.  
#16-1 Jinhui Road, Jinsha Community, Kengzi Sub-District,  
Pingshan New District, 518122 Shenzhen, PEOPLE'S REPUBLIC  
OF CHINA

**Product Category(ies): Digital Electrocardiograph, Patient Monitor,  
B-Ultrasonic Diagnostic Equipment,  
Doppler Fetal Heart Rate Detector, Infusion  
Pump, Syringe Pump, Fingertip Pulse  
Oximeter, Handheld Pulse Oximeter,  
Fetal/Maternal Monitor, Fetal Monitor, Color  
Doppler Ultrasound System, Central  
Monitoring System, Ambulatory  
Electrocardiographs, Ambulatory blood  
pressure recorders, and associated  
software.**

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.:** BJ1989607  
**Valid from:** 2019-09-11  
**Valid until:** 2024-05-26

**Date,** 2019-09-11

Stefan Preiß  
Head of Certification/Notified Body

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ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT



# Certificate

No. Q5 065758 0005 Rev. 01

**Holder of Certificate:** **Shenzhen Biocare Bio-Medical Equipment Co., Ltd.**

#16-1 Jinhui Road, Jinsha Community, Kengzi Sub-District  
Pingshan New District  
518122 Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.  
#16-1 Jinhui Road, Jinsha Community, Kengzi Sub-District,  
Pingshan New District, 518122 Shenzhen, PEOPLE'S REPUBLIC  
OF CHINA

**Certification Mark:**



**Scope of Certificate:**

**Design and Development, Production and Distribution of Digital Electrocardiograph, B-Ultrasonic Diagnostic Equipment, Patient Monitor, Fetal Monitor, Doppler Fetal Heart Rate Detector, Infusion Pump, Syringe Pump, Fingertip Pulse Oximeter, Handheld Pulse Oximeter, Ambulatory electrocardiographs, Ambulatory blood pressure recorder and associated software, Fetal/Maternal Monitor, Color Doppler Ultrasound System, Central Monitoring System.**

**Applied Standard(s):**

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

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

**Report No.:** BJ20089601

**Valid from:** 2020-04-01

**Valid until:** 2023-03-31

**Date,** 2020-03-17

Christoph Dicks

Head of Certification/Notified Body



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip		Введите текст для поиска...										
1.3. Certificat CE	Certificat CE	Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
1.2. Declarati de conform CE	Declarati de conform CE				IE 300			biocare				
		DM000042090	ELECTROCARDIOGRAF DIGITAL		IE 300		China	SHENZHEN BIO-CARE BIO-MEDICAL EQUIPMENT CO., LTD.	RAILSMED S.R.L.	A07.PS-01.Rg04-8	10-01-2018	
<input checked="" type="checkbox"/> <a href="#">Содержит('Denumire','') И Содержит('Producatorul','biocare') И Содержит('Model','IE...</a>												

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