CONTEC™

CMS50QA/QB

Pulse Oximeter

Contec Medical Systems Co.,Ltd.

ADD: No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE ' S REPUBLIC OF CHINA
Tel：0086-335-8015430
Fax：0086-335-8015588
E-mail：cms@contecmed.com.cn contec88@gmail.com
Website：http://www.contecmed.com

CMS50QA/QB

CMS50QA/QB Pulse Oximeter is a portable equipment adopting advanced technology, it mainly checks SpO_2 and PR value through the finger, which provides advanced, non-invasive and scientific means for quantitative measurement of oxygen saturation.

CMS50QA/QB is fit for family, hospital, oxygen bar, community healthcare, physical care in sports (It can be used before or after doing sports and it is not recommended to use the device during the process of having sport) and etc.

Features

- Easy and convenient in operation.
- Small in volume, light in weight and convenient in carrying.
- Low power consumption.
- Small appearance,more fit for children.
- SpO_2 value display.
- Pulse rate value display, bar graph display.
- Pulse waveform display (only CMS50QB).
- With screen overturn function (only CMS50QB).
- Pulse sound indication.
- Low-voltage indication.
- Data beyond limits indication.
- Perfusion Index (optional)

Accessories

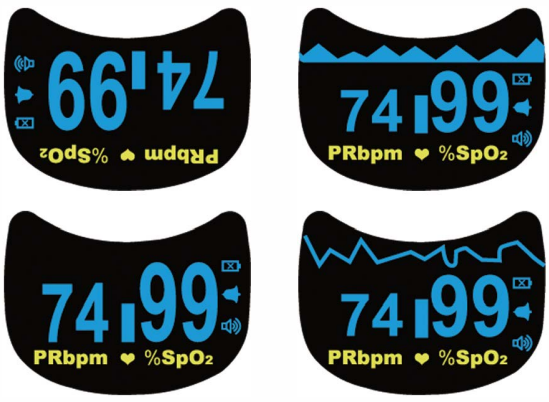
- One rechargeable buttony battery
- Charge accessories: One power adapter , one charger , one data line
- One user manual
- One lanyard

Performance

- SpO_2 measurement range: 0%~100%
  Accuracy: 70%~100%: ± 2%
  0%~69%: unspecified
- PR measurement range: 30bpm~250bpm
  Accuracy: ± 2bpm or ± 2%, (select larger) .
- Resolution:
  SpO_2: 1%
  PR: 1bpm
- **Measurement Performance in Weak Filling Condition**: SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ± 2 bpm or ± 2%(select larger) .
- **Resistance to surrounding light**: The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.
- Power supply: 3.6 V DC~4.2V DC.
- Safety classification: Interior Battery, BF Type.

Physical characteristic

- Dimension: 46(L) × 40(W) × 29(H) mm
- Weight: About 35g (with a rechargeable buttony battery)



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und 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 050972 0050 Rev. 04

Manufacturer:

Contec Medical Systems Co., Ltd.
No.112 Qinhuang West Street
Economic& Technical Development Zone
066004 Qinhuangdao, Hebei Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Patient Monitor, Fetal Monitor, B-Ultrasound Diagnostic System, Pulse Oximeter, Electrocardiograph, Pocket Fetal Doppler, Visual Electronic Stethoscope, Multi-functional Visual Stethoscope, Dynamic ECG Systems, Digital Brain Electric Activity Mapping, Infusion Pump, Spirometer, Ambulatory Blood Pressure Monitor, Electronic Sphygmomanometer, EMG/EP System, Portable ECG Monitor, Temperature Probe, Pulse Oximeter Probe, Tele Pulse Oximeter, Tele Breather, Multi-parameter Vital Signs Monitor, Sleep apnea screen meter, Oxygen concentrator, ECG Workstation, Wearable Monitor, Mesh Nebulizer, Capnograph and Infrared Thermometer.**

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.:	BJ20090203
Valid from:	2020-06-17
Valid until:	2024-05-26

Date, 2020-06-17

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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

MANUFACTURER:	**CONTEC MEDICAL SYSTEMS CO., LTD** No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	Pulse Oximeter, CMS50QB
CLASSIFICATION - ANNEX IX:	Class Ⅱb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ excluding chapter 4

WE, （CONTEC MEDICAL SYSTEMS CO., LTD）HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 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 MANUFACTURE.

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 M NCHEN, GERMANY
IDENTIFICATION NUMBER:	CE 0123
(EC) CERTIFICATE(S):	G1 050972 0050 Rev.04
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2010-09-30 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2020-06-18
SIGNATURE:	President

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

Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	EN 60601-1-2:2007 (IEC60601-1-2:2007)	Medical electrical equipment- Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
3	EN 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
4	IEC 60601-1-8:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance -Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
5	EN 62304:2015	Medical device software-Software life-cycle processes
6	EN60601-1-11:2010 (IEC 60601-1-11:2010)	Medical electrical equipment--Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
7	EN 62366:2015	Medical devices - Application of usability engineering to medical devices
8	ISO 80601-2-61: 2011	Medical electrical equipment —Part 2-61:Particular requirements for basic safety and essential performance of pulse oximeter equipment

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 050972 0052 Rev. 03

Holder of Certificate: **Contec Medical Systems Co., Ltd.**
No.112 Qinhuang West Street
Economic& Technical Development Zone
066004 Qinhuangdao, Hebei Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Sales, Installation and Servicing of Dynamic EEG Systems, Dynamic ECG Systems, Digital Brain Electric Activity Mapping, Patient Monitor, Patient Monitor System, B-Ultrasound Diagnostic System, ECG Recorder, ECG Workstation, ECG Monitor System, Medical Image Workstation, Fetal Monitor, Ventilator, Anesthetic Machine, High Frequency Surgical Unit, Pulse Oximeter, Pocket Fetal Doppler, Visual Stethoscope, Electric Suction Apparatus, Transcranial Doppler Analysis System, Maternal/Fetal Monitor, Infusion Pump, Spirometer, Ambulatory Blood Pressure Monitor, Electronic Sphygmomanometer, EMG/EP System, Pulse Oximeter Probe, Temperature Probe, ECG Electrode Cable And Accessories, Blood Pressure Cuff, Portable ECG Monitor, Semi-auto Biochemistry Analyzer, Urine Analyzer, Oxygen concentrator, Multi-parameter Vital Signs Monitor, Remote ECG Monitor, Sleep apnea screen meter, Arteriosclerosis Detector, Compressor Nebulizer, Wearable Monitor, Predictive Thermometer, Mesh Nebulizer, Capnograph and Infrared Thermometer.**

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.: BJ20090203
Valid from: 2020-06-17
Valid until: 2022-03-01

Date, 2020-06-17

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 050972 0052 Rev. 03

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):

Contec Medical Systems Co., Ltd.
No.112 Qinhuang West Street, Economic& Technical Development Zone, 066004 Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA

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

TÜV®