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 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

Digitally signed by Potînga Stela
Date: 2021.08.19 15:21:54 EEST
Reason: MoldSign Signature
Location: Moldova

Stefan Preiß
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

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A4 / 07.17

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

Product Service

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

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

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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:	*PATIENT MONITOR* *TYPE: iM 12 iM 15* *GMDN CODE: 33586*
CLASSIFICATION - *ANNEX IX*:	*CLASS IIB, 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*
EC REP EUROPEAN REPRESENTATIVE:	*SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE)* *Eiffestraße 80, 20537 Hamburg, GERMANY*

START OF CE-MARKING: *2015-07-02*

PLACE, DATE OF DECLARATION:	*SHENZHEN P.R.C., 2019-09-19*
SIGNATURE:	_____ *NAME:CHENJUN* *POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)*