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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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

Stefan Preiß
Head of Certification/Notified Body

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