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.

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Valid until:	2024-05-26

Digitally signed by Potînga Stela
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Date, 2019-09-11

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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