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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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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

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

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