



# Certificate

No. Q5 065758 0005 Rev. 02

**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

**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.**

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:Q5 065758 0005 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 065758 0005 Rev. 02)

**Report No.:** BJ22089602  
**Valid from:** 2023-04-01  
**Valid until:** 2026-03-31

**Date,** 2023-03-07

Christoph Dicks  
Head of Certification/Notified Body

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**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):** **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

See Scope of Certificate