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D-ZM-11321-01-00

Product Service

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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:

tuv-sud.com/ps-cert

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17