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CERTIFICATE

No. Q1N 16 07 64548 014

Holder of Certificate: Biomedical Instruments Co., Ltd.

> Room 4C1, F2.6 Tianzhan Building Tianan Chegongmiao Industrial Zone

Futian District 518042 Shenzhen

PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Biomedical Instruments Co., Ltd.

> Room 4C1, F2.6 Tianzhan Building, Tianan Chegongmiao Industrial Zone, Futian District, 518042 Shenzhen, PEOPLE'S REPUBLIC OF

CHINA

Certification Mark:



Scope of Certificate: **Design and Development,**

Production and Distribution of

Holter System, PC ECG,

Ambulatory Blood Pressure System

Applied

EN ISO 13485:2012 + AC:2012

Standard(s): Medical devices - Quality management systems -

Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009) DIN EN ISO 13485:2012

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.

SH1632210 Report No.:

Valid from: 2016-10-20 Valid until: 2019-10-19

Date, 2016-07-28

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Stefan Preiß

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