EC DECLARATION OF CONFORMITY

We, **Biomedical Instruments Co., Ltd..**, located at Room 4C1, F2.6 Tianzhan Building, Tianan Chegongmiao Industrial Zone, Futian District, Shenzhen 518042 China; as the manufacturer of below stated product(s), hereby declare with sole responsibility that below listed product(s) comply with the essential requirements and provisions of **Council Directive 93/42/EEC** concerning medical devices as amended by 2007/47/EC. All supporting documentations are retained under the premises of the the manufacturer.

Product : Ambulatory Blood Pressure System includes TeleABP monitor and software as well as accessories

Brand : BI

Model(s) : BI5000、BI5000B

Classification : IIa according to Rule 10

Conformity Assessment Route : Annex V.3

Date of first CE-marking with own name : 2016-02-02

Notify Body : TÜV SÜD Product Service GmbH
Ridlerstr 65 80339 Munich Germany.

EC Certificate Number : G2 18 01 64548 017

Valid until : 2023-03-31

Notify Body identification Number : CE0123

EU Representative : Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Issued by : Biomedical Instruments Co., Ltd.
Room 4C1, F2.6 Tianzhan Building, Tianan Chegongmiao Industrial Zone, Futian District, Shenzhen 518042 China.

Authorized Signature : ..... / General Manger

Place, Date : Shenzhen / 2018.03.07

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 18 01 64548 017

Manufacturer:

Biomedical Instruments Co., Ltd.
Room 4C1, F2.6 Tianzhan Building
Tianan Chegongmiao Industrial Zone
Futian District
518042 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Holter System, PC ECG, Ambulatory Blood Pressure System

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH18322EXT01

Valid from: 2018-04-01
Valid until: 2023-03-31

Date, 2018-02-02

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123