Biomedical Instruments Co., Ltd.

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, and also comply with the REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023. Please refer to the Self-declaration for details. All supporting documentations are retained under the premises of the the manufacturer.

Product : Holter System
(Including Holter recorder and EcgLab analysis software)

Brand : BI

Model(s) : BI9900、BI9100

Classification : IIa according to Rule 10

Conformity Assessment Route : Annex V.3

Date of first CE-marking with own name : 2017-10-18

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
Extension of the transitional period until: 2028-12-31

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 Manager
Place, Date : Shenzhen / 2023-03-22