EC Declaration of Conformity

EC Certificate Full Quality Assurance System: TW10/00535

For the following equipment:

Product Name	**Product Code** (or other unambiguous reference)
Non-invasive Automatic Blood Pressure ECG Monitor	BP700X/BX-700/BX-705/BX-710/BX-715/ BP750X/BX-800/BX-805/BX-810/BX-815
Non-invasive Automatic Blood Pressure Monitor	BP700B/BP700C/BM-701/BM-702/BM-711/ BM-712/BM-801/BM-802/BM-811/BM-812
ECG Pen	850E/870E/ 880E

is here with confirmed to comply with the requirements set out in the Council

Directive on the harmonization of the Laws of the Mémber States concerning Medical Device Directive 93/42/EEC (as amended by Directive 2007/47/EC). Annex II excluding sec.4 and assessed by the Notified Body SGS Belgium NV limited (NB number: 1639, Address: SGS House Noorderlaan 87 2030 Antwerp Belgium) and responsible for approving and controlling the ISO 13485 quality system

For the evaluation regarding the Class II (a) product safety aspects, the following standards were applied,

The classification is made in accordance with Directive 93/42/EEC(as amended by Directive 2007/47/EC), section 3, 3.2, rule 10. “Active device intended for diagnosis are in class II a, if they are intended to allow direct diagnosis or monitoring of vital physiological process.”

and conforms to the following European standards:

General standards:

EN 60601-1:2006/A1:2013, EN 60601-1-11:2010, EN 60601-1-2 : 2015,
EN 60601-1-4: 1996/A1:1999, EN 60601-1-6:2010, EN 62366:2008,
EN 62304:2006/AC:2008, EN ISO 14155:2011, EN ISO 10993-1 : 2010,
EN ISO 10993-5 : 2009, EN ISO 10993-10: 2010, EN ISO 15223-1:2016,

EN 1041 : 2008, EN ISO 14971 : 2012, EN ISO 13485 : 2016

ECG Pen and Non-invasive Automatic Blood Pressure ECG Monitor applicable standards:

EN 60601-2-25: 1995/A1:1999, EN 60601-2-47:2001

Non-invasive Automatic Blood Pressure ECG Monitor and Non-invasive Automatic Blood Pressure Monitor applicable standards:

EN 1060-3:1997+A2:2009, EN 1060-4: 2004

Bluetooth devices applicable standards (excluded ECG Pen 850E and Non-invasive Automatic Blood Pressure Monitor BP700C)

ETSI EN 300 328 V.2.1.1:2016-11, ETSI EN 301 489-1 V2.1.1: 2017-02 ,

ETSI EN 301 489-17 V3.1.1:2017-02

The following EU - representative is explicitly designated to act as our sole

Authorized Representative:

SGS Belgium NV

(Company Name)

SGS House Noorderlaan 87 2030 Antwerp Belgium

(Company Address)

Person responsible for making this declaration:

MD Biomedical, Inc. / MD Biomedical (Foshan) Co., Ltd.

(Manufacturer Name)

8F., No.222, Sec 4, Chengde Rd., Taipei City 111, Taiwan, R.O.C. /
Room 408/409/410-5, Building 3, Tian-an Nanhai Digital Town, No. 1 Jien Ping Rd., Guicheng St., Nanhai Dist., Foshan City, Guandong, China

(Place, Manufacture Address)

Chairman		May 12, 2020
(Position/Title)	**(Signature/Stamp)**	**(Date)**

Attachment I

Conformity declaration Radio Equipment directive (RED)

To ensure conformity with current legislation we, Beurer GmbH, declare the following on behalf of our sales partner Bio Medical Inc.

The products mentioned in the table above meet the standards of the Radio Equipment directive (RED) EU 2014/53. They are tested and meet the standards mentioned below.

ETSI EN 300 328 V.2.1.1:2016-11, ETSI EN 301 489-1 V2.1.1: 2017-02 ,

ETSI EN 301 489-17 V3.1.1:2017-02

Ulm, 2025-06-05

Marco Bühler, Managing Director
Beurer GmbH