File No.TO-DBP01- 17

EU Declaration of Conformity

Manufacturer:
JOYTECH Healthcare Co., Ltd.
No. 365. Wuzhou Road, 311100 Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA
Single Registration Number: CN-MF-000006020

whose single Authorized Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Single Registration Number:DE-AR-000000001

We, the manufacturer, herewith declare that the products
Product Name: Blood Pressure Monitor
Model: All models as table below:

Type	**Model**	**Basic UDI-DI**:
Arm-Type models without wireless function	DBP-6191, DBP-6175, DBP-6177, DBP-6179, DBP-6173, DBP-6181, DBP-6182, DBP-6185, DBP-6192, DBP-6193, DBP-61A0, DBP-61A2, DBP-61A3, DBP-61A4, DBP-6194, DBP-6195, DBP-6196, SBM53, DBP-61C5, DBP-61C5L, DBP-61D0, DBP-61D0L, DBP-61D5, DBP-61D5L , DBP-61D6, DBP-61D6L, DBP-61E6, DBP-61E7, DBP-61A1, DBP-6186,DBP-61D2L , DBP-61F4, DBP-61F4L, DBP-61D8L, DBP-61D9L, DBP-61E1, DBP-61E2, DBP-61E3, DBP-61F5	6970392211BP0004YB
Arm-Type models without wireless function, for the pregnant	DBP-61D2L-P, DBP-61F4-P, DBP-61F4L-P, DBP-61D8L-P, DBP-61D9L-P, DBP-61E1-P, DBP-6173-P, DBP-6179-P, DBP-6193-P, DBP-6194-P, DBP-6195-P, DBP-6196-P, DBP-61A0-P, DBP-61A1-P,DBP-61E2-P,DBP-61E3-P	6970392211BP0009YM
Arm-Type models with wireless function	DBP-6279B, DBP-6273B, DBP-6275B, DBP-62C5B, DBP-62C5L, DBP-6277B,DBP-6281B,DBP-6282B,DBP-6285B,DBP-6292B,DBP-6293B,DBP-6293L, DBP-62D5L, DBP-62D5B, DBP-62D6L, DBP-62D6B, DBP-62D0B, DBP-62D0L, DBP-6281L, DBP-6282L, DBP-6285L, DBP-62A1B, DBP-62A2B, DBP-62A3B, DBP-62A4B, DBP-6294B, DBP-6295B, DBP-6296B, BM 92, DBP-62E7B, DBP-6286B, DBP-62D2L,DBP-62F4B , DBP-62F4L, DBP-62D8L, DBP-62D9L, DBP-62E1B, DBP-62E3B,	6970392211BP0005YD
Arm-Type models with wireless function , for the pregnant	DBP-62D2L-P, DBP-62F4B-P , DBP-62F4L-P, DBP-62D8B-P, DBP-62D9L-P, DBP-6273B-P,DBP-6279B-P, DBP-6293B-P, DBP-6293L-P, DBP-6294B-P, DBP-6295B-P, DBP-6296B-P, DBP-62A1B-P DBP-62E1B-P, DBP-62E3B-P,DBP-61E2B-P	6970392211BP0010Y6
Wrist-Type models without Bluetooth	DBP-8176H, DBP-8178, DBP-8188, DBP-8189, DBP-8197, DBP-8198, DBP-8199, DBP-81A5, DBP-81A6, SBC35, DBP-81E4, DBP-81E5,DBP-81F2	6970392211BP0006YF
Wrist-Type models with Bluetooth	SBC45, DBP-8276H, DBP-8278B, DBP-8288B, DBP-82A5B, DBP-82A6B, DBP-8297B, DBP-8298B, DBP-8299B, DBP-82E4B	6970392211BP0007YH

Common Specifications: Not Available.

UMDNS-Code: 16173 EMDN-*Code*: Z1203020501

covered by the present declaration is in conformity with this Regulation (EU) 2017/745 on medical device and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

The medical device has been assigned to **class IIa by rule 10 according** to Annex Ⅷ of the (EU) 2017/745 MDR. It bears the mark

CE 0123

The product concerned has been evaluated under technical files compliance according to Annex Ⅱ and Annex Ⅲ, and manufactured under a quality management system according to Annex Ⅸ of (EU) 2017/745 MDR. All supporting documentation is retained at the premises of the manufacturer.

Compliance of the designated product with the (EU) 2017/745 MDR has been assessed and certified by the Notified Body

TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany
Certificate No.: **G10 109940 0002**
Initial issue date: 2022-04-28
Valid from: 2025-09-23
Valid until: 2027-04-27
Notified body identified number:0123

following the procedure relating to the EU Declaration of Conformity set out in Annex Ⅳ of (EU) 2017/745 MDR.

Compliance of the designated product with RoHS 2011/65/EU

Conformity to European Parliament and Council Directive 2011/65/EU on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) with its Amendments (EU) 2015/86. Standards Applied: EN IEC 63000:2018

Compliance of other standards refer to the following:

No.	Standards	
1	EN 60601-1-2:2015+A1:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
2	EN 60601-1:2006/A2:2021	General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
3	EN 60601-1-11:2015/A1:2021	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
4	EN 60601-1-6:2010/A2:2021	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5	EN 62366-1:2015/A1:2020	Medical devices - Application of usability engineering to medical devices
6	EN 62304:2006/AC:2008+A1:2015	Medical device software - Software life-cycle processes
7	EN ISO 10993-1: 2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
8	EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

9	EN ISO 10993-10:2023	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity
10	EN ISO 14971:2019/A1:2021	Medical devices - Application of risk management to medical devices
11	EN ISO 15223-1: 2021	Symbols for use in the labeling of medical devices
12	EN ISO 20417:2021	Information to be supplied by the manufacturer
13	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
14	IEC 80601-2-30:2018 EN IEC 80601-2-30:2019	Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers
15	ISO 81060-2:2018+A2:2024 EN ISO 81060-2:2019/A2:2024	Non-Invasive Sphygmomanometers - Part2: Clinical Investigation Of Automated Measurement Type

The above mentioned declaration of conformity is exclusively under the responsibility of
Company: **JOYTECH Healthcare Co., Ltd.**

Hangzhou, 2025-09-23

Place , date

JOYTECH HEALTHCARE CO.,LTD
浙江健拓医疗仪器科技有限公司

Legally binding signature, title
Yunhua Ren, General Manager

Declaration of Identity

To Whom it may Concern,

We, JOYTECH Healthcare Co., Ltd., located at No. 365. Wuzhou Road, 311100 Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA, as the manufacturer of Blood pressure monitors(SBC 39, SBC35) hereby declares all the test reports for SBC35 are also applicable for SBC 39, since the only difference between SBC35 and SBC39 is appearance, which will not influence the safety and effectiveness performance.

The above mentioned declaration of conformity is exclusively under the responsibility of Company: **JOYTECH Healthcare Co., Ltd.**

Hangzhou, 2025-09-05

Place , date

JOYTECH HEALTHCARE CO.,LTD
浙江健拓医疗仪器科技有限公司

Legally binding signature, title
Yunhua Ren, General Manager