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 Bluethooth	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	6970392211BP0004YB
Wrist-Type models without Bluethooth	DBP-8176H, DBP-8178, DBP-8188, DBP-8189, DBP-8197, DBP-8198, DBP-8199, DBP-81A5, DBP-81A6	6970392211BP0006YF

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, HRB 85742
Certificate No.: **G10 109940 0002**
Issue date: 2022-04-28
Expiry date: 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.

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

Hangzhou, 2023-3-20

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