

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 with wireless function , for the pregnant	DBP-62D8B-P	6970392211BP0010Y6

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



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 Rev.06**
 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 RED 2014/53/EU

Conformity to the essential requirements of the legislation 2014/53/EU the radio equipment
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directive, RED have been demonstrated by using the following standards:

EN 301 489-1 V2.2.3:2019
EN 301 489-17 V 3.3.1:2024
EN 300 328 V2.2.2:2019
EN 62479:2010
EN 50663:2017

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 the designated product with REACH

Conformity to Total Cadmium Content –Reference to Regulation (EC) No. 1907/2006 Annex XVII Entry 23
Total Lead Content – Reference to Regulation (EC) No. 1907/2006 Annex XVII Entry 63
Polycyclic Aromatic Hydrocarbons (PAHs) Content – Regulation (EC) No. 1907/2006 Annex XVII Entry 50, Point 5
Nonylphenol ethoxylates (NPEO) Content - Reference to Regulation (EC) No. 1907/2006, Annex XVII, Entry 46a
Phthalates Content – Reference to regulation (EU) 2018/2005 amending regulation (EC) No. 1907/2006, Annex XVII Entry 51 & 52
Aromatic Amines Content from Azo Colorants - Regulation (EC) No. 1907/2006 Annex XVII Entry 43, Points 1 & 2
Candidate List of Substances of Very High Concern for authorization published by European Chemicals Agency (ECHA) Regarding Regulation (EC) No. 1907/2006 concerning REACH

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

Hangzhou, 2026-05-11

Place, date

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