

## EU Declaration of Conformity

Certificate No.: MLHBP2024062801

*Manufacturer:*

Microlife Corporation  
9F, No. 431, RuiGuang Road, NeiHu  
Taipei, 114, Taiwan, R.O.C.  
Single Registration Number(SRN): TW-MF-000010688

*Whose single Authorized Representative:*

Microlife UAB  
P. Lukšio g. 32  
08222 Vilnius, Lithuania  
Single Registration Number(SRN): LT-AR-000011673

We, the manufacturer, herewith declare that the product  
**Digital Non-invasive Blood Pressure Monitor for Home Use Series**  
**Basic-UDI-DI: 4719003HBPCF**  
**Customer Model Name: BP B1 Standard**  
**Manufacturer Model Name: BPHJA2-0 (BP B0 Basic)**

**Class: IIa**  
**Trade Name: Microlife**  
**EMDN Code: Z1203020501, GMDN Code: 45617**

**Intended purpose:**

This device measures blood pressure (systolic and diastolic) and pulse rate, with an optional function for detecting the presence of atrial fibrillation (AFIB) during measurement.

meets the provisions of Medical Device Regulation (EU) 2017/745 which apply to them.

The medical device has been assigned to class IIa according to Annex VIII Rule 10 of the Medical Device Regulation (EU) 2017/745.

It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex IX of Medical Device Regulation (EU) 2017/745.

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

**SGS Belgium NV**  
**Noorderlaan 87 2030 Antwerp Belgium**  
Certificate No.: TW23/00000625  
Validity from: 2023-12-21 Expiry date: 2028-08-24

following the procedure relating to the EU Declaration of Conformity set out in Annex IV of Medical Device Regulation (EU) 2017/745, and in conformity to the following standards or other normative documents:

EN 60601-1:2006+A2:2021(IEC 60601-1:2005+AMD1:2012+AMD2:2020)  
EN 60601-1-2:2015+A1:2021(IEC 60601-1-2:2014+AMD1:2020)  
EN 60601-1-11:2015+A1:2021(IEC 60601-1-11:2015+AMD1:2020)  
EN 60601-1-6:2010+A1:2015+A2:2021(IEC 60601-1-6:2010+AMD1:2013+AMD2:2020)  
EN 62366-1:2015+AC:2015+AC:2016+A1:2020(IEC 62366-1:2015+AMD1:2020)  
EN IEC 80601-2-30:2019(IEC 80601-2-30:2018)  
EN 62304:2006+A1:2015(IEC 62304:2006+AMD1:2015)  
EN ISO 10993-1:2020(ISO 10993-1:2018)  
EN ISO 10993-5:2009(ISO 10993-5:2009)  
EN ISO 10993-10:2023(ISO 10993-10:2021)  
EN ISO 10993-12:2021(ISO 10993-12:2021)  
EN ISO 14971:2019+A11:2021(ISO 14971:2019)  
EN ISO 15223-1:2021(ISO 15223-1:2021)  
ISO 20417:2021

EN ISO 13485:2016+A11:2021  
ANSI/AAMI/ISO 81060-2:2019  
MEDDEV 2.7/1 revision 4  
2011/65/EU amended by M81 (2023/171) and corrected by C2  
EC/1907/2006 amended by M74 (2023/1464) and corrected by C9  
EN ISO 14155:2020(ISO 14155:2020)

The above mentioned declaration of conformity is issued under the sole responsibility of Microlife Corporation, and this declaration is valid until August 24, 2028.

Place and Date of issue: Taipei

  
*Steve Li*  
*Product Manager*

  
*Ariel Wang*  
*Management Representative, PRRC*