microlife®

EU Declaration of Conformity

Certificate No.: MLHBP2025022601

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

Whose single Swiss Authorized Representative:
Microlife AG
Espenstrasse 139, 9443 Widnau ,
Switzerland
Single Registration Number(SRN): CHRN-AR-20002880

We, the manufacturer, herewith declare that the products
Digital Non-invasive Blood Pressure Monitor for Home Use Series **Class: IIa**
Basic-UDI-DI: 4719003HBPCF **Trade Name: Microlife**
Please refer to the following model.

Model No. (Commercial Product Name)	EMDN Code	GMDN Code
BPHJA2-0 (BP B1 Standard)	Z1203020501	45617

Intended purpose:
These devices measure blood pressure (systolic and diastolic) and pulse rate, with an optional function for detecting the presence of atrial fibrillation (AFIB) during measurement.

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

These medical devices have been assigned to class IIa according to Annex VIII Rule 10 of the Medical Device Regulation (EU) 2017/745.
It bears the mark

CE 1639

The products concerned have 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
Since from: 2023-08-24 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+A1:2013+AC:2014+A12:2014+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 10993-23:2021(ISO 10993-23:2021)

EN ISO 14971:2019+A11:2021(ISO 14971:2019)
EN ISO 15223-1:2021(ISO 15223-1:2021)
ISO 20417:2021
EN ISO 14155:2020(ISO 14155:2020)
EN ISO 81060-2:2019(ISO 81060-2:2018)
MEDDEV 2.7/1 revision 4
2011/65/EU amended by M84 (2024/232) and corrected by C3
EC/1907/2006 amended by M77 (2024/1328) and corrected by C9
MDCG 2019-16 Rev.1 Guidance on Cybersecurity for medical devices
EN ISO 13485:2016+A11:2021

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



2025.02.26

Ariel Wang

Management Representative, PRRC