

EU Declaration of Conformity

Certificate No.: MLHBP2024012502

Manufacturer:
 Microlife Corporation
 9F, 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 products
 Digital Non-invasive Blood Pressure Monitors for Home Use Series
 Basic-UDI-DI: 4719003HBPCF

Class: IIa
Trade Name: Microlife

Customers type no.	Manufacturer type no.	EMDN Code	GMDN Code	AFIB
BP A1 Easy	BP A1 Easy (ERP BP3GR1-1P)	Z1203020501	45617	No
BP A2 Basic	BP A2 Basic (ERP BP3GQ1-3P)	Z1203020501	45617	No
BP A3L Comfort	BP A3L Comfort (ERP BP3GX1-3A)	Z1203020501	45617	No
BP A6 PC	BP A6 PC (ERP BP3GU1-8Y)	Z1203020501	64511	Yes
BP A6 BT	BP A6 BT (ERP BP3GU1-7B)	Z1203020501	64511	Yes
BP A7 Touch	BP A7 Touch (ERP BP3GT1-6Y)	Z1203020501	64511	Yes
BP A200 AFIB	BP A200 AFIB (ERP BP3MS1-4Y)	Z1203020501	64511	Yes
BP N2 Easy	BP N2 Easy(ERP BP3GQ1-1H)	Z1203020501	47489	No
BP N1 Basic	BP N1 Basic(ERP BP3GA1-2H)	Z1203020501	47489	No
BP B2 Basic	BP B2 Basic (ERP BP3KA1-3N)	Z1203020501	45617	No
BP B3 Comfort	BP B3 Comfort (ERP BP3KT1-4N)	Z1203020501	45617	No
BP B6 Connect	BP B6 Connect(ERP BP3KV1-5X)	Z1203020501	64511	Yes
BP W1 Basic	BP W1 Basic (ERP BP3GI1-3E)	Z1203020501	45617	No
BP A7 Touch BT	BP A7 Touch BT (ERP BP3GT1-6F)	Z1203020501	64511	Yes
BP B1 Classic	BP B1 Classic (ERP BP3KE1-3E)	Z1203020501	45617	No

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.

The 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



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 have 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: 2028-8-24

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) or EN 60601-1:2006+A1:2013+AC: 2014 (IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012(or IEC60601-1:2012))
EN 60601-1-2:2015+A1:2021(IEC 60601-1-2:2014+AMD1:2020) or EN 60601-1-2:2015 (IEC 60601-1-2:2014)
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+A1:2015)
2014/53/EU
EN ISO 10993-1:2020(ISO 10993-1:2018)
EN ISO 10993-5: 2009(ISO 10993-5: 2009)
EN ISO 10993-10:2021(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
DIN EN ISO 81060-2:2018(EN ISO 81060-2:2019(ISO 81060-2:2018))
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
MDCG 2019-16 Guidance on Cybersecurity for medical devices
MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745
EN ISO 14155:2011 (ISO 14155:2011)

The above mentioned declaration of conformity is issued under the sole responsibility of Microlife Corporation, and this declaration is valid until 2028.8.24.

Place and Date of issue: Taipei, 25 Jan 2024



Ariel Wang
Management Representative, PRRC