

## EU Declaration of Conformity

Certificate No.: MLCAN20250218

*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

**Products: Aneroid Sphygmomanometer Series**

**EMDN: C9006**

**Basic UDI-DI: 4719003ANRR**

**Trade Name: Microlife**

**Model: BPAG1-10, BPAG1-20, BPAG1-30, BPAG1-40**

**Class: Im**

**Intended Use:**

Aneroid Sphygmomanometer is a non-automated, mechanical blood-pressure monitor that used for the indirect measurement (noninvasive) and display of arterial blood pressure.

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

These medical devices have been assigned to class Im according to Annex VIII Rule 10 of the Medical Device Regulation (EU) 2017/745 and Article 3.1.6 of MDCG 2021-24.

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 has been assessed and certified by the Notified Body

**SGS Belgium NV**

**Noorderlaan 87 2030 Antwerp Belgium**

Certificate No.: TW23/00000625

Validity from: 02 September 2024 Expiry date: 24 August 2028

following the procedure relating to the EU Declaration of Conformity set out in Article 19 and Annex IV of Medical Device Regulation (EU) 2017/745, and in conformity to the following standards or other normative documents:

EN ISO 81060-1:2012 (ISO 81061-1:2007)

EN ISO 14971: 2019+A11:2021 (ISO 14971: 2019)

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 62366-1:2015+AC:2015+AC:2016+A1:2020 (IEC 62366-1:2015+AMD1:2020)

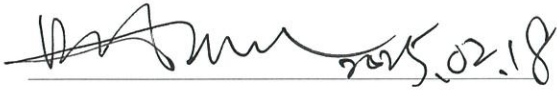
MEDDEV 2.7/1 revision 4

EN ISO 13485:2016+A11:2021

EN ISO 20417:2021 (ISO 20417:2021)

EN ISO 15223-1:2021 (ISO 15223-1:2021)

The above mentioned declaration of conformity is issued under the sole responsibility of Microlife Corporation, and this declaration is valid until 18<sup>th</sup> February 2026.

 2025.02.18

Robert Dern, Product Manager, Issued Date

MICROLIFE CORPORATION

 2025.02.18

Authorized Signatures  
Ariel Wang, Global RA & QM Director, Issued Date