microlife

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
Basic UDI-DI: 4719003ANRR
Model: BPAG1-10, BPAG1-20, BPAG1-30, BPAG1-40
EMDN: C9006
Trade Name: Microlife
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

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
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)

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

2025.02.18

Robert Dern, Product Manager, Issued Date

MICROLIFE CORPORATION

Authorized Signature(s)

2025.02.18

Ariel Wang, Global RA & QM Director, Issued Date