

EU Declaration of Conformity

Certificate No.: MLCUFF2025091101

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 products
Cuff for oscillometric non-invasive blood pressure monitors, reusable
Basic UDI-DI: 4719003CUFFZD

Class: I
Trade Name: Microlife

Device Model Family	Model Number	Reference Number	EMDN Code	GMDN Code
CA0	CA0-S0-514	WatchBP Single-Patient Cuff S	Z1203020599	34978
CA0	CA0-M0-513	WatchBP Single-Patient Cuff M	Z1203020599	34978
CA0	CA0-L0-512	WatchBP Single-Patient Cuff L	Z1203020599	34978

Intended Use:

This device, a reusable cuff, is an accessory of oscillometric non-invasive blood pressure monitors, when used together, is intended to measure human brachial blood pressure non-invasively for monitoring of the systolic and diastolic pressures, to support the diagnosis medical conditions or diseases related to blood pressure (e.g. hypertension).

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

The medical device accessory has been assigned to class I according to Annex VIII Rule 1 section 4.1 in Chapter III of the Medical Device Regulation (EU) 2017/745.
It bears the mark



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 IEC 80601-2-30:2019(IEC 80601-2-30:2018)
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 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)
ISO 15223-1:2021/Amd.1:2025
ISO 20417:2021
EN ISO 81060-2:2019(ISO 81060-2:2018)
MEDDEV 2.7/1 revision 4
EN ISO 14155:2020(ISO 14155:2020)
2011/65/EU amended by M85 ((EU) 2024/1416) and corrected by C3 ((EU) 2023/1526)
EC/1907/2006 amended by M80 ((EU) 2025/660) and corrected by C9 (2021/1297)
EN ISO 13485:2016+A11:2021

The above mentioned declaration of conformity is issued under the sole responsibility of Microlife Corporation. The validity of this declaration expires in case of a revised declaration of conformity.

microlife

Place and Date of issue: Taipei

A handwritten signature in black ink, appearing to read 'Jimmy Deng', followed by the date '11.05.09' written in a similar cursive style.

Jimmy Deng
Management Representative, PRRC