

## EU Declaration of Conformity

Document No.: MLCUFF2026050601

**Manufacturer:**

**Microlife Corporation**  
9F, No. 431, RuiGuang Road, NeiHu,  
Taipei, 114, Taiwan, R.O.C.

Single Registration Number(SRN): TW-MF-000010688  
000011673

**Whose single Authorized Representative:**

**Microlife UAB**  
P. Lukšio g. 32  
08222 Vilnius, Lithuania

Single Registration Number(SRN): LT-AR-

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**

Commercial Product Name	Model Number	EMDN Code	GMDN Code
WatchBP Home S cuff	cuff-S-WBPH	Z1203020599	34978
WatchBP Home M cuff	cuff-M-WBPH	Z1203020599	34978
WatchBP Home L cuff	cuff-L-WBPH	Z1203020599	34978
WatchBP Home L-XL cuff	cuff-LXL-WBPH	Z1203020599	34978
WatchBP O3 S cuff	cuff-S-WBPA	Z1203020599	34978
WatchBP O3 S cuff	cuff-S-WBPA-C	Z1203020599	34978
WatchBP O3 M cuff	cuff-M-WBPA	Z1203020599	34978
WatchBP O3 M cuff	cuff-M-WBPA-C	Z1203020599	34978
WatchBP O3 L cuff	cuff-L-WBPA	Z1203020599	34978
WatchBP O3 L cuff	cuff-L-WBPA-C	Z1203020599	34978
WatchBP O3 L-XL cuff	cuff-LXL-WBPA	Z1203020599	34978
WatchBP O3 L-XL cuff	cuff-LXL-WBPA-C	Z1203020599	34978
WatchBP Office S cuff	cuff-S-WBPO	Z1203020599	34978
WatchBP Office M cuff	cuff-M-WBPO	Z1203020599	34978
WatchBP Office L cuff	cuff-L-WBPO	Z1203020599	34978
WatchBP Office L-XL cuff	cuff-LXL-WBPO	Z1203020599	34978
WatchBP Office M size cuff Ankle	cuff-M-WBPO-Ankle	Z1203020599	34978
WatchBP Office L size cuff Ankle	cuff-L-WBPO-Ankle	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

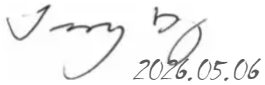


following the procedure relating to the EU Declaration of Conformity set out in Article 19 and Annex IV of Medical Device Regulation (EU) 2017/745, and in conformity to the following standards or other normative documents:

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)-ROHS Direction  
EC/1907/2006 amended by M82 ((EU) 2025/1731) and corrected by C10 (2023/2055)-REACH Regulation  
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.

Place and Date of issue: Taipei



**Jimmy Deng**  
**Management Representative, PRRC**