microlife®

# EU Declaration of Conformity

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*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**

| 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

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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

2026.05.06

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