microlife

EU Declaration of Conformity

Certificate No.: MLCCUFF2023061301

Manufacturer:
Microlife Corporation
9F, 431, RuiGuang Road, NeiHu,
Taipei, 11492, 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

Trade Name: Microlife
Class: I

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).

Commercial Product Name	Cuff Model Family Number	Cuff Catalog Number
Microlife Soft Cuff S	CA3	CA3-S0-978
Microlife Soft Cuff S	CA3	CA3-S0-998
Microlife Rigid Cuff M-L	CA5	CA5-W0-980
Microlife Soft Cuff M-L	CA3	CA3-W0-975
Microlife Rigid Cuff M-L	CA5	CA5-W0-997
Microlife Rigid Cuff M-L	CA5	CA5-W0-980
Microlife Soft Cuff M	CA3	CA3-M0-979
Microlife Soft Cuff M	CA3	CA3-M0-979
Microlife Soft Cuff M	CA3	CA3-M0-999
Microlife Soft Cuff L-XL	CA3	CA3-Z0-A02
Microlife Soft Cuff L-XL	CA3	CA3-Z0-A45
Microlife Soft Cuff L-XL	CA3	CA3-Z0-997
Microlife Soft Cuff L	CA3	CA3-L0-976

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

CE

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 80601-2-30:2010+A1:2015 (IEC 80601-2-30:2009+A1:2013)
EN 60601-1-6:2010+A1:2015 (IEC 60601-1-6:2010+A1:2013)
EN 62366-1:2015 (IEC 62366-1:2015)
EN ISO 10993-1:2020(ISO 10993-1:2018)
EN ISO 10993-5:2009 (ISO 10993-5:2009)
ISO 10993-10:2021
EN ISO 10993-12:2021(ISO 10993-12:2021)

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EN ISO 14971: 2019+A11:2021(ISO 14971:
2019)
EN ISO 15223-1:2016 (ISO15223-1:2016)
EN ISO 13485:2016
DIN EN ISO 81060-2:2018(EN ISO 81060-2:2019(ISO 81060-2:2018))
ISO 20417:2021
MEDDEV 2.7/1 revision 4
2011/65/EU amended by M80 (2022/1632) and corrected by C2
EC/1907/2006 amended by M71(2022/586) and corrected by C9

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

Steve Li 2023.6.14
Steve Li, Product Manager, Issued Date

Wang 2023.06.14
Ariel Wang, Global RA & QM Director, Issued Date