EU Declaration of Conformity

Certificate No.: MLCIRPC1002023060101

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
Microlife Probe Cover of Infrared Ear Thermometer
Class: I **Trade Name: Microlife**
Model Name: IR PC100 **Basic-UDI-DI: 4719003IRPC33**
Intended purpose: Probe covers are single-use protective caps used as accessories for the Microlife Infrared Ear Thermometer.

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 ISO 13485:2016
ISO 80601-2-56:2017+A1:2018
EN 60601-1-6:2010/A1:2015 (IEC60601-1-6:2010+A1:2013)
EN 62366-1:2015(IEC 62366-1:2015)
EN ISO 10993-1:2009/AC: 2010 (ISO10993-1:2009+ COR.1:2010)
EN ISO 10993-5:2009(ISO10993-5:2009)
EN ISO 10993-10:2013 (ISO10993-10:2010)
EN ISO 10993-12:2012 (ISO10993-12:2012)
EN ISO 14971: 2012(ISO14971: 2007)
EN ISO 15223-1:2016(ISO15223-1:2016)
ISO 20417:2021
MEDDEV 2.7/1 rev 4
EC/1907/2006
2011/65/EU

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.

6/1'23

Michael Wang, Product Manager, Issued Date

2023.06.01

Ariel Wang, Global RA & QM Director, Issued Date