

EC Declaration of Conformity

Certificate No.: ML20230620003

Manufacturer:

Microlife Corporation
9F, 431, RuiGuang Road, NeiHu,
Taipei, 11492, Taiwan, R.O.C.

whose single Authorized Representative:

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

We, the manufacturer, herewith declare that the products/product category
Atrial fibrillation-detection blood pressure monitor GMDN ---
BP3KT1-3N (BP B3 AFIB)

meet the provisions of Directive 93/42/EEC amended by 2007/47/EC and Regulation (EU) 2017/745 Article 120(3), which apply to them.

The medical device has been assigned to class IIa according to Annex IX rule 10 of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

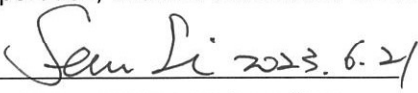
TÜV NORD CERT GmbH
Langemarckstraße 20 45141 Essen
Certificate No.: 04 232 950010

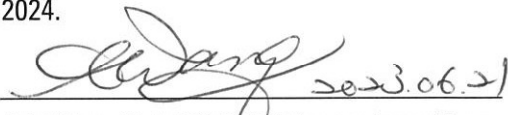
Validity from: 2019-10-22 Expiry date: 2024-05-26

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC, and in conformity to the following standards or other normative documents:

EN1060-1: 1995+A2:2009
EN1060-3: 1997+A2:2009
EN1060-4: 2004
EN 80601-2-30:2010+A1:2015(IEC 80601-2-30:2009+A1:2013)
EN 60601-1:2006+A1:2013+AC:2014+A12:2014+A2:2021(IEC 60601-1:2005+AM1:2012+AMD2:2020)
EN 60601-1-2:2015+A1:2021(IEC 60601-1-2:2014:AMD1:2020)
EN 60601-1-11:2015(IEC 60601-1-11:2015)
EN 62304:2006+A1:2015 (IEC 62304:2006+AMD1:2015)
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)
EN ISO 14971: 2012(ISO 14971: 2007)
EN ISO 15223-1:2016(ISO 15223-1:2016)
EN1041:2008+A1:2013

The above mentioned declaration of conformity is exclusively under the responsibility of Microlife Corporation, and this declaration is valid until May 26, 2024.


Steve Li, Product Manager, Issued Date


Ariel Wang, Global RA & QM Director, Issued Date