

EC Declaration of Conformity

Certificate No.: ML20230915003

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 ---
BP3MX1-3 (WatchBP Home A)

meets 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:

EN IEC 80601-2-30:2019(IEC 80601-2-30:2018)
EN ISO 81060-2:2019(ISO 81060-2:2018)
MEDDEV 2.7/1 revision 4
EN 60601-1-2:2006+A1:2013+AC: 2014(IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012(or IEC60601-1:2012))
EN 60601-1-2:2015(IEC 60601-1-2:2014)
EN 60601-1-11:2015/A1:2021(IEC 60601-1-11:2015/A1:2020)
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)
EN ISO 10993-10: 2013(ISO 10993-10:2010)
EN ISO 10993-12:2012 (ISO 10993-12:2012)
EN ISO 14971:2019/A11:2021(ISO 14971:2019)
EN ISO 15223-1:2016(ISO 15223-1:2016)
EN 1041:2008+A1:2013

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

Ray Lei 2023/09/18

Ray Lei, Product Manager, Issued Date

Ariel Wang 2023/09/18

Ariel Wang, Global RA & QM Director, Issued Date