microlife

EC Declaration of Conformity

Certificate No.: ML20230630009

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

Automatic-inflation electronic shpygmomanometer, portable, arm/wrist (Blood pressure measurement, electronic)
BP3KT1-4X (BP B3 Comfort PC)

GMDN 45617

meet the provisions of Directive 93/42/EEC 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

CE 0044

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
Langemarckstr. 20, DE-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 80601 -2-30:2010/A1:2015 (IEC 80601-2-30:2009/A1 :2013)
DIN EN 81060-2:2018(EN ISO 81060-2:2019(ISO 81060-2:2018))
EN 60601-1:2006+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 (IEC 60601-1-11:2015)
EN 62304:2006+A1:2015 (IEC 62304:2006+A1:2015)
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, this declaration is valid until May 26, 2024.

Sem Li 2023.7.3

Steve Li, Product Manager, Issued Date
Microlife Corporation

2023.07.03

Ariel Wang, Global RA & QM Director, Issued Date
Microlife Corporation