

EC Declaration of Conformity

Certificate No.: ML20230704001

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 product/product category

**Infrared patient thermometer, ear
IR1DF1-1(IR 150)**

GMDN 17887

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

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
Langemarckstraße 20, 45141 Essen

Certificate No.: 04 232 950010

Validity from: 2019-10-22

until: 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:

ISO 80601-2-56:2017+A1:2018

EN 60601-1:2006+A1:2013+AC: 2014(IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012(or IEC 60601-1:2012))

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(IEC62304:2006+AMD1:2015)

EN 60601-1-6:2010+A1:2015(IEC60601-1-6:2010+A1:2013)

EN 62366-1:2015(IEC 62366-1:2015)

EN ISO 10993-1:2020(ISO 10993-1:2018)

EN ISO 10993-5: 2009(ISO 10993-5: 2009)

ISO10993-10:2021


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 issued under the sole responsibility of Microlife Corporation, and this declaration is valid until May 26, 2024.


Michael Wang, Product Manager, Issued Date


Ariel Wang, Global RA & QM Director