

# EC Declaration of Conformity

Certificate No.: ML20230727005

*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, skin**  
**FR1MF1**

**GMDN 17888**

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

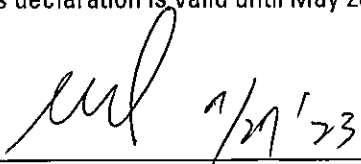
Validity from: 2019-10-22

until: 2024-05-26

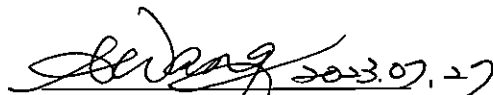
following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC, and in conformity to the following standards or other normative documents:

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)  
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+AMD1:2015)  
EN 60601-1-6:2010+A1:2015(IEC 60601-1-6:2010+AMD1:2013)  
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 10993-10:2023(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)  
EN 1041:2008+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*