

EC Declaration of Conformity

Certificate No.: ML20210527001

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

Responsible importer:
THUASNE
 27 Rue de la Jomayère
 42100 Saint-Étienne, FRANCE

We, the manufacturer, herewith declare that the products
Infrared patient thermometer, skin GMDN 17888

Customers type no.:	Manufacturers type no.:
Thermomètre Thuasne sans contact, W1360	FR1MA1

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



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 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+A1:2015)
- EN 60601-1-6:2010/A1:2015(IEC 60601-1-6:2010+A1:2013)
- EN 62366-1:2015(IEC 62366-1:2015)
- ISO 80601-2-56:2017+A1:2018
- EN ISO 10993-1:2009/AC: 2010(ISO10993-1:2009+ COR.1:2010)
- EN ISO 10993-5:2009(ISO10993-5:2009)
- EN ISO 10993-10:2013(ISO10993-10:2010)
- EN ISO 10993-12:2012(ISO10993-12:2012)
- EN ISO 14971:2012(ISO14971: 2007)
- EN ISO 15223-1:2016(ISO15223-1:2016)
- EN 1041:2008

The above-mentioned declaration of conformity is exclusively under the responsibility of

Microlife Corporation



 Ariel Wang, Global RA & QM Director

May 28th, 2021

 Issued Date