

EC Declaration of Conformity

Certificate No.: ML20220113001

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 Distributor:

Rudolf Riester GmbH
Bruckstr. 31
72417 Jungingen
Germany

We, the manufacturer, herewith declare that the products
Intermittent electronic patient thermometer GMDN 14035

Customers type no.:	Manufacturers type no.:
ri-gital	MT3001

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:

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 60601-1-6:2010+A1:2015(IEC 60601-1-6:2010+A1:2013)
EN 62366-1:2015(IEC 62366-1:2015)
EN ISO 10993-1:2009+AC: 2010(ISO 10993-1:2009+COR.1:2010)
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 14971:2012(ISO 14971: 2007)
EN ISO 15223-1:2016(ISO 15223-1:2016)
EN 1041:2008

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


Albert Huang, Product Management Director, Issued Date


Ariel Wang, Global RA & QM Director, Issued Date