microlife®

EC Declaration of Conformity

Certificate No.: ML20260702001

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
Intermittent electronic patient thermometer GMDN 14035

Model No. (Commercial Product Name)	GMDN Code
MT19F1(MT19F1)	14035

meet 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
Am TÜV 1 45307 Essen Germany
Certificate No.: 04 232 950010
Validity from: 2019-10-22 Expiry date: 2024-05-26
Validity extended till: 2028-12-31

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+A12:2014+A2:2021(IEC 60601-1:2005+AMD1:2012+AMD2:2020)
EN 60601-1-2:2015+A1:2021(IEC 60601-1-2:2014+AMD1:2020)
EN 60601-1-11:2015+A1:2021(IEC 60601-1-11:2015+AMD1:2020)
EN 60601-1-6:2010+A1:2015+A2:2021(IEC 60601-1-6:2010+AMD1:2013+AMD2:2020)
EN 62366-1:2015+AC:2015+AC:2016+A1:2020(IEC 62366-1:2015+AMD1:2020)
EN 62304:2006+A1:2015(IEC 62304:2006+A1:2015)
EN ISO 10993-1:2020(ISO 10993-1:2018)
EN ISO 10993-5: 2009(ISO 10993-5: 2009)
EN ISO 10993-10:2023(ISO10993-10:2021)
EN ISO 10993-12:2021(ISO 10993-12:2021)
EN ISO 10993-23:2021(ISO 10993-23:2021)
EN ISO 14971:2019+A11:2021(ISO 14971:2019)
EN ISO 15223-1:2021+A1:2025(ISO 15223-1:2021+A1:2025)
EN 1041:2008+A1:2013
2012/19/EU(WEEE) Directive

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The above mentioned declaration of conformity is exclusively under the responsibility of Microlife Corporation, and this declaration is valid until December 31, 2028.

Samuel 2026.7.2

Samuel Huang, Product Manager, Issued Date
Microlife Corporation

2026.07.02

Jimmy Deng, Global RA & QM Director, Issued Date
Microlife Corporation