

EU Declaration of Conformity

Document No.: MLIFR2026012101

Manufacturer:

Microlife Corporation
9F, No. 431, RuiGuang Road, NeiHu
Taipei, 114, Taiwan, R.O.C.
Single Registration Number (SRN): TW-MF-000010688

Whose single Authorized Representative:

Microlife UAB
P. Lukšio g. 32
08222 Vilnius, Lithuania
Single Registration Number (SRN): LT-AR-000011673

We, the manufacturer, herewith declare that the products
Digital Infrared Thermometer Series
Basic-UDI-DI: 4719003IRSR
Please refer to the following for model list.

Class: IIa
Trade Name: Microlife

Model No. (Commercial Product Name)	EMDN Code	GMDN Code
FR1MF1 (NC150)	V0301010202	17888
FR1MF1-B (NC150 BT)	V0301010202	17888
IR1DF1-1 (IR150)	V0301010202	17887

Intended purpose:

The devices are intended to measure body temperature

meet the provisions of Medical Device Regulation (EU) 2017/745 which apply to them.

These medical devices have been assigned to class IIa according to Annex VIII Rule 10 of the Medical Device Regulation (EU) 2017/745.

It bears the mark



The products concerned have been designed and manufactured under a quality management system according to Article 52(6) and Annex IX (Chapters I and III, including Section 4) of Medical Device Regulation (EU) 2017/745.

Compliance of the designated product with the Medical Device Regulation (EU) 2017/745 has been assessed and certified by the Notified Body

SGS Belgium NV
Noorderlaan 87 2030 Antwerp Belgium
Certificate No.: TW23/00000625
Since from: 2023-08-24 Expiry date: 2028-08-24

following the procedure relating to the EU Declaration of Conformity set out in Annex IV of Medical Device Regulation (EU) 2017/745, 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) or 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 ISO 80601-2-56:2017+A1:2020(ISO 80601-2-56:2017+A1:2018)
EN 62304:2006+A1:2015(IEC 62304:2006+AMD1:2015)
EN ISO 10993-1:2020(ISO 10993-1:2018)
EN ISO 10993-5:2009(ISO 10993-5:2009)

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EN ISO 10993-10:2023(ISO 10993-10:2021)
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(ISO 15223-1:2021)
2014/53/EU (Radio Equipment Directive)
ISO 20417:2021
ISO 17664-2:2021
MEDDEV 2.7/1 revision 4
EN ISO 14155:2020(ISO 14155:2020)
2011/65/EU amended by M85 ((EU) 2024/1416) and corrected by C3 ((EU) 2023/1526)-RoHS Directive
EC/1907/2006 amended by M82 ((EU) 2025/1731) and corrected by C10 (2023/2055)-REACH Regulation
EN ISO 13485:2016+A11:2021
2012/19/EU (WEEE) Directive
MDCG 2019-16 Rev. 1 Guidance on Cybersecurity for medical devices
MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU)2017/745

The above mentioned declaration of conformity is issued under the sole responsibility of Microlife Corporation, and this declaration is valid until August 24, 2028.

Place and Date of issue: Taipei



2026.01.21

Jimmy Deng
Management Representative, PRRC