microlife

EU Declaration of Conformity

Certificate No.: MLMT2024012501

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 Thermometer Series
Basic UDI-DI: 4719003MTT9-

Class: IIa
Trade Name: Microlife

Customers type no.:	Manufacturers type no.:	EMDN Code	GMDN Code
MT 300	MT 300 (ERP MT16I1)	V0301010201	14035
MT 400	MT 400 (ERP MT1P11)	V0301010201	14035
MT 800	MT 800 (ERP MT18R1)	V0301010201	14035
MT16C2	MT16C2	V0301010201	14035
MT16F1	MT16F1R	V0301010201	14035
MT1931	MT1931	V0301010201	14035
MT1951	MT1951	V0301010201	14035
MT1961	MT1961	V0301010201	14035

Intended purpose: The devices are intended to measure body temperature.

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

The 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

CE 1639

The products concerned have been designed and manufactured under a quality management system according to Annex IX of Medical Device Regulation (EU) 2017/745.

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

SGS Belgium NV
Noorderlaan 87 2030 Antwerp Belgium
Certificate No.: TW23/00000625
Validity from: 2023-12-21 Expiry date: 2028-8-24

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+A12:2014+A2:2021(IEC 60601-1:2005+AMD1:2012+AMD2:2020) or EN 60601-1:2006+A1:2013+AC: 2014 (IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012(or IEC60601-1:2012))
EN 60601-1-2:2015+A1:2021(IEC 60601-1-2:2014+AMD1:2020) or EN 60601-1-2:2015 (IEC 60601-1-2:2014)
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 80601-2-56:2017+A1:2020(ISO 80601-2-56:2017+A1:2018)
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 14971: 2019+A11:2021(ISO 14971: 2019)
EN ISO 15223-1:2021(ISO 15223-1:2021)
EN ISO 13485:2016+A11:2021

ISO 20417:2021
ISO 17664-1:2021
MEDDEV 2.7/1 revision 4
2011/65/EU amended by M81 (2023/171) and corrected by C2
EC/1907/2006 amended by M74 (2023/1464) and corrected by C9

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

Place and Date of issue: Taipei, 25 Jan 2024

Ariel Wang
Management Representative, PRRC