

EU Declaration of Conformity

Certificate No.: MLMT2024112101

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: 697038816MT3V

Class: IIa

Please refer to the following model list.

Commercial Product Name	ERP number	EMDN Code	GMDN Code
DIGItemp E3 15	MT1682	V0301010201	14035
DIGItemp E3 15 - ECO	MT1682	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.

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 Annex IX 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+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)
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)
ISO 20417:2021
ISO 17664-2:2021
MEDDEV 2.7/1 revision 4
2011/65/EU amended by M84 (2024/232) and corrected by C3
EC/1907/2006 amended by M77 (2024/1328) and corrected by C9
EN ISO 13485:2016+A11:2021

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

Handwritten signature of Michael Wang in black ink, with the date '11/21/21' written below it.

Michael Wang
Product Manager

Handwritten signature of Ariel Wang in black ink, with the date '2024. 11. 22' written below it.

Ariel Wang
Management Representative, PRRC