microlife

EC Declaration of Conformity

Certificate No.: ML20230710003

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
MT1PG1(MT850)

meets 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 V 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
Langemarckstraße 20 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 V of Directive 93/42/EEC, and in conformity to the following standards or other normative documents:

EN ISO 80601-2-56:2017+A1:2020(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(or IEC 60601-1:2012)
EN 60601-1-2:2015(IEC 60601-1-2:2014)
EN 60601-1-11:2015(IEC 60601-1-11:2015)
EN 62304:2006+A1:2015 (IEC 62304:2006+AMD1:2015)
EN 60601-1-6:2010+A1:2015(IEC 60601-1-6:2010+A1:2013)
EN 62366-1:2015(IEC 62366-1:2015)
EN ISO 10993-1:2020(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 14971:2012(ISO 14971: 2007)
EN ISO 15223-1:2016(ISO 15223-1:2016)
EN 1041:2008+A1:2013
MEDDEV 2.7/1 revision 4

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

7/12/23

Michael Wang, Product Manager, Issued Date
Microlife Corporation

2023.07.12

Ariel Wang, Global RA& QM Director, Issued Date
Microlife Corporation