EC Declaration of Conformity

Certificate No.: ML20230711001

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 product/product category
Infrared patient thermometer, ear **GMDN 17887**
IR1MQ1 (IR 310)

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 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
Langemarckstraße 20, 45141 Essen
Certificate No.: 04 232 950010
Validity from: 2019-10-22
until: 2024-05-26

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(IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012)
EN 60601-1-2:2015(IEC 60601-1-2:2014)
EN 60601-1-11:2015(IEC 60601-1-11:2015)
EN 60601-1-6:2010/A1:2015(IEC 60601-1-6:2010+A1:2013)
EN 62366-1:2015(IEC 62366-1:2015)
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 14971:2012(ISO 14971:2007)
EN ISO 15223-1:2016(ISO 15223-1:2016)
EN1041:2008+A1:2013
The above mentioned declaration of conformity is issued under the sole responsibility of Microlife Corporation, and this declaration is valid until May 26, 2024.

9/11/23
Michael Wang, Product Manager, Issued Date

2023.07.11
Ariel Wang, Global RA & QM Director

Microlife Corporation
9F, No. 431, RuiGuang Road,
NeiHu, Taipei, 114,
Taiwan, R.O.C.

27Th March 2024

Confirmation Letter Reference: CLNB1639 – TW/TPE/613065

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer

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

AND

Manufacturer: ONBO Electronic (Shenzhen) Co., Ltd.
No.138, Huasheng Road, Langkou Community, Dalang Street,
Longhua District, Shenzhen,
CHINA
SRN Number: CN-MF-000013782

Authorized representative: Microlife UAB
P. Lukšio g. 32
08222 Vilnius,
Lithuania

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Digital Non-invasive Blood Pressure Monitor for Home Use Series Basic UDI-DI Microlife Corporation - 4719003HBPCF ONBO Electronic (Shenzhen) Co., Ltd. – 697038816HBPSE	Class IIa	N/A	Microlife Corporation Certificate # 04 232 950010 (Rev.4); NB0044 ONBO Electronic (Shenzhen) Co. Ltd. Certificate # 44 232 202393 (Rev.1); NB0044
Digital Non-invasive Blood Pressure Monitors for Professional Use Series Basic UDI-DI Microlife Corporation - 4719003OBPDJ ONBO Electronic (Shenzhen) Co., Ltd. - 697038816OBPTH	Class IIa	N/A	Microlife Corporation Certificate # 04 232 950010 (Rev.4); NB0044 ONBO Electronic (Shenzhen) Co. Ltd. Certificate # 44 232 202393 (Rev.1); NB0044
Blood Pressure Long-term Ambulatory Recorder Series Basic UDI-DI Microlife Corporation - 4719003ABPBC	Class IIa	N/A	Microlife Corporation Certificate # 04 232 950010 (Rev.4); NB0044 ONBO Electronic (Shenzhen) Co. Ltd.

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
ONBO Electronic (Shenzhen) Co., Ltd. - 697038816ABPRB			Certificate # 44 232 202393 (Rev.1); NB0044
Digital Infrared Thermometer Series Basic UDI-DI Microlife Corporation - 4719003IRSR ONBO Electronic (Shenzhen) Co., Ltd. - 697038816IR3D	Class IIa	N/A	Microlife Corporation Certificate # 04 232 950010 (Rev.4); NB0044 ONBO Electronic (Shenzhen) Co. Ltd. Certificate # 44 232 202393 (Rev.1); NB0044
Digital Thermometer Series Basic UDI-DI Microlife Corporation - 4719003MTT9 ONBO Electronic (Shenzhen) Co., Ltd. - 697038816MT3V	Class IIa	N/A	Microlife Corporation Certificate # 04 232 950010 (Rev.4); NB0044 ONBO Electronic (Shenzhen) Co. Ltd. Certificate # 44 232 202393 (Rev.1); NB0044
Digital Peak Flow Meters Series Basic UDI-DI Microlife Corporation - 4719003PFSN ONBO Electronic (Shenzhen) Co., Ltd. -	Class IIa	N/A	Microlife Corporation Certificate # 04 232 950010 (Rev.4); NB0044 ONBO Electronic (Shenzhen) Co. Ltd. Certificate # 44 232 202393 (Rev.1); NB0044

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
697038816PF3A			
Aneroid Sphygmomanometer Series Basic UDI-DI Microlife Corporation - 4719003ANRR	Class Im	N/A	Microlife Corporation Certificate # 04 232 950010 (Rev.4); NB0044

*The devices associated with this Basic UDI-DI are listed in the Appendix.

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/12	Version 1	Initial issue
2024/03/27	Version 2	Review of reference numbers covered

Appendix

Digital Non-invasive Blood Pressure Monitor for Home Use Series **Basic UDI-DI –** **Microlife Corporation: 4719003HBPCF** **ONBO Electronic (Shenzhen) Co., Ltd.: 697038816HBPSE**		
BP3AG1 (BP3AG1)	BP3GU1-8B (BP A6 BT)	BP3KT1-4F (BP B3 Plus)
BP3BC1-3P (BP W90)	BP3GU1-8Y (BP A6 PC)	BP3KT1-4N (BP B3 Comfort)
BP3GA1-2H (BP N1 Basic)	BP3GX1-2N (BP A3 Easy)	BP3KT1-4X (BP B3 Comfort PC)
BP3GC1-5B (BP A5 BT)	BP3GX1-3A (BP A3L Comfort)	BP3KV1-5B (BP B6 Advanced Connect)
BP3GC1-5F (BP A5 AFIB)	BP3GX1-3N (BP A3L Basic)	BP3KV1-5N (BP B6 Favourite)
BP3GC1-5Y (BP A5 PC)	BP3GX1-3X (BP A3L PC)	BP3KV1-5X (BP B6 Connect BT)
BP3GI1-3E (BP W1 Basic)	BP3GX1-4N (BP A3 Basic)	BP3MK1-3 (BP W100)
BP3GK1-4E (BP W2 Slim)	BP3GX1-5N (BP A3 Plus)	BP3MK1-2D (BP3MK1-2D)
BP3GP1-1L (BP N3 Basic / VSA Cradle)	BP3GX1-5X (BP A3 PC)	BP3MS1-2D (BP A150 2G)
BP3GQ1-1H (BP N2 Easy)	BP3KA1-1E (BP B2 Easy)	BP3MS1-4F (BP A150 3G-30)
BP3GQ1-1P (BP A2 Easy)	BP3KA1-3N (BP B2 Basic)	BP3MS1-4K (BP A200 2G)
BP3GQ1-3P (BP A2 Basic)	BP3KB1-3E (BP W3 Comfort)	BP3MS1-4Y (BP A200 AFIB)
BP3GR1-1P (BP A1 Easy)	BP3KE1-3E (BP B1 Classic)	BP3MX1-1 (WatchBP Home)
BP3GR1-3P (BP A1 Basic)	BP3KM1-3N (BP W10)	BP3MX1-3 (WatchBP Home A)
BP3GT1-6F (BP A7 Touch BT)	BP3KN1-3B (BP W70 BT)	BP3MX1-3C (WatchBP Home A BT)
BP3GT1-6Y (BP A7 Touch)	BP3KN1-3N (BP W70)	BP3MX1-4 (WatchBP Home N)
BP3GU1-3E (BP A6 Advanced Easy)	BP3KT1-3E (BP B3 AFIB Advanced)	BP3MX1-5 (WatchBP Home S)
BP3GU1-6B (BP A6 Basis Plus BT)	BP3KT1-3F (BP B3 Basic)	BP3T01-1B (BP Progress)
BP3GU1-6L (BP A6 Basis)	BP3KT1-3N (BP B3 AFIB)	BP3UG1-2E (BP A2 Classic)
BP3GU1-7B (BP A6 BT)	BP3KT1-4B (BP B3 BT)	BP3UG1-2S (BP A2 Standard)
BP3GU1-7F (BP A6 Basic)		
Digital Non-invasive Blood Pressure Monitors for Professional Use Series **Basic UDI-DI –** **Microlife Corporation: 4719003OBPDJ** **ONBO Electronic (Shenzhen) Co., Ltd.: 697038816OBPTH**		
BP3SK1-3B (WatchBP Office 2G)	TWIN200 ABI (WatchBP Office ABI)	TWIN200 VSR (WatchBP Office Vascular)
TWIN100 (ProBP 2400)	TWIN200 AFS (WatchBP Office AFIB)	
Blood Pressure Long-term Ambulatory Recorder Series **Basic UDI-DI –** **Microlife Corporation: 4719003ABPBC** **ONBO Electronic (Shenzhen) Co., Ltd.: 697038816ABPRB**		
BP3MZ1-1 (WatchBP O3 1G)	BP3MZ1-1A (WatchBP O3 AFIB 1G)	BP3SZ1-1 (WatchBP O3 2G)
Digital Infrared Thermometer Series **Basic UDI-DI –** **Microlife Corporation: 4719003IRSR**		

ONBO Electronic (Shenzhen) Co., Ltd.: 697038816IR3D		
FR1DG1 (NC200)	FR1MF1-B (NC150 BT)	IR1DN1 (IR210)
FR1DS1 (NC400)	FR1MY1 (NC300)	IR1DN1-1 (IR200)
FR1MA1 (NC100)	IR1DF1-1 (IR150)	IR1MQ1 (IR310)
FR1MF1 (NC150)		
Digital Thermometer Series **Basic UDI-DI –** **Microlife Corporation: 4719003MTT9** **ONBO Electronic (Shenzhen) Co., Ltd.: 697038816MT3V**		
MT1611 (MT1611)	MT17M1 (MT720)	MT19U1 (MT19U1)
MT1621 (MT1621)	MT1811 (MT1811)	MT1P11 (MT400)
MT1622 (MT1622)	MT1831 (MT1831)	MT1P11AM (MT410)
MT16B1 (MT16B1)	MT18P1 (MT18P1)	MT1PD1R (MT1PD1R)
MT16C2 (MT16C2)	MT18R1 (MT800)	MT1PG1 (MT850)
MT16I1 (MT300)	MT1921 (MT1921)	MT1PJ1 (MT808)
MT16K1 (MT50/60)	MT1931 (MT1931)	MT1PM1 (MT500)
MT16Z1 (MT600)	MT1951 (MT1951)	MT1PN1 (MT550)
MT17K1 (MT700)	MT1961 (MT1961)	MT3001 (MT3001)
MT17L1 (MT710)	MT19M1 (MT200)	MT3001AM (MT3010)
Digital Peak Flow Meters Series **Basic UDI-DI –** **Microlife Corporation: 4719003PFSN** **ONBO Electronic (Shenzhen) Co., Ltd.: 697038816PF3A**		
PF200 (PF100)	PF200 (PF200)	
Aneroid Sphygmomanometer Series **Basic UDI-DI –** **Microlife Corporation: 4719003ANRR**		
BP AG1-10 (BP AG1-10)	BP AG1-30 (BP AG1-30)	
BP AG1-20 (BP AG1-20)	BP AG1-40 (BP AG1-40)	