

EG-Zertifikat / EC-Certificate

gem. 93/42/EWG Anhang II ohne (4) / acc. 93/42/EEC Annex II without (4)

Hiermit wird bescheinigt, dass die Firma / This certifies, that the company

Microlife Corporation

9F, 431, RuiGuang Road, NeiHu
Taipei 11492
Taiwan, R.O.C.

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

für weitere Fertigungsstätten, Niederlassungen: siehe Anlage 2 / for additional sites: see annex 2

Elektronische Thermometer, nicht invasive Blutdruckmessgeräte mit und ohne AF-Erkennung, Flowmeter und Aneroid Sphygmomanometer inkl. Stethoskope

Electronic Thermometers, Non-invasive Blood Pressure Monitors with and without AF-Detection, Peak Flow Meters and Aneroid Sphygmomanometers incl. Stethoscopes

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennnummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / Reg.-No. 04 232 950010
Bericht Nr. / Report No. 3524 9335

Gültigkeit / Validity
von / from 2019-10-22
bis / until 2024-05-26
Edition 4



Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-10-17

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



ANLAGE / ANNEX

Anlage 1, Blatt 1 von 3
Annex 1, page 1 of 3

Reg.-Nr. / Reg. No. 04 232 950010

Produkte der Klasse IIa
Products of class IIa

GMDN

Automatisch arbeitendes elektronisches
Blutdruckmessgerät, tragbar, Arm/Handgelenk
*Automatic-inflation electronic sphygmomanometer,
portable, arm/wrist*

45617

Manuell arbeitendes elektronisches
Blutdruckmessgerät, tragbar
*Manual-inflation electronic sphygmomanometer,
portable*

47489

Blutdruckmessgerät mit AF-Erkennung
*Atrial fibrillation-detection blood pressure
monitor*

Ambulanter Langzeit-Blutdruckschreiber
Blood pressure long-term ambulatory recorder

36888

Bericht Nr. / Report No. 3524 9335

Gültigkeit / Validity
von / from 2019-10-22
Edition 5



Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-10-17

TÜV NORD CERT GmbH

Langemarckstraße 20

45141 Essen

www.tuev-nord-cert.de

medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / ANNEX

Anlage 1, Blatt 2 von 3
Annex 1, page 2 of 3

Reg.-Nr. / Reg. No. 04 232 950010

Produkte der Klasse IIa
Products of class IIa

GMDN

Elektronisches Kurzzeit-Patiententhermometer
Intermittent electronic patient thermometer

14035

Elektronisches Dauer-Patiententhermometer
*Continuous electronic patient thermometer,
battery-powered*

14034

Infrarotthermometer, Ohr
Infrared patient thermometer, ear

17887

Infrarotthermometer, Haut
Infrared patient thermometer, skin

17888

Atemgrenzwertmesser, elektronisch
Peak flow meter, electronic

46906

Bericht Nr. / Report No. 3524 9335

Gültigkeit / Validity
von / from 2019-10-22
Edition 5



Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-10-17

TÜV NORD CERT GmbH

Langemarckstraße 20

45141 Essen

www.tuev-nord-cert.de

medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / ANNEX

Anlage 1, Blatt 3 von 3
Annex 1, page 3 of 3

Reg.-Nr. / Reg. No. 04 232 950010

Produkte der Klasse Im
Products of class Im

GMDN

Aneroid-Blutdruckmessgerät, manuell
Aneroid manual sphygmomanometer

16156

Anmerkung: Für Produkte der Klasse I mit Messfunktion beschränkt sich das Zertifizierungsverfahren auf die Herstellungsschritte in Zusammenhang mit der Konformität der Produkte mit den messtechnischen Anforderungen.

Note: For products of class I with measuring functions the certification process is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

Bericht Nr. / Report No. 3524 9335

Gültigkeit / Validity
von / from 2019-10-22
Edition 5



Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-10-17

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / ANNEX

Anlage 2, Blatt 1 von 1
Annex 2, page 1 of 1

Reg.-Nr. / Reg. No. 04 232 950010

Weitere Fertigungsstätte/Niederlassungen
Additional sites

**ONBO Electronic (Shenzhen) Co., Ltd.
No. 138 Huasheng Road, Langkou Community,
Dalang Street, Longhua District, Shenzhen,
China**

Bericht Nr. / Report No. 3524 9335

Gültigkeit / Validity
von / from 2019-10-22
Edition 4

M.H. 7/8

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2019-10-17

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / Notified Body ID. No. 0044



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16



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 <u>Basic UDI-DI</u> 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 <u>Basic UDI-DI</u> 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 <u>Basic UDI-DI</u> 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 <u>Basic UDI-DI</u> 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 <u>Basic UDI-DI</u> 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 <u>Basic UDI-DI</u> 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 <u>Basic UDI-DI</u> 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)
MT1611 (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)	