EU Quality Management System Certificate TW23/00000625

The management system of

Microlife Corporation

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

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 17 December 2025 until 24 August 2028 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 24 February 2028

Issue 7. Certified since 24 August 2023

Authorised by
Virginie Siloret
Head of Certification and Compliance

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EU Quality Management System Certificate
TW23/00000625, continued

Microlife Corporation

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIa devices - MDA0203, MDS1009, MDS1010

Blood Pressure Long-term Ambulatory Recorder Series
Basic UDI-DI: 4719003ABPBC

Digital Non-invasive Blood Pressure Monitor Series
Basic UDI-DI:4719003HBPCF

Digital Infrared Thermometer Series
Basic UDI-DI:4719003IRSR

Digital Thermometer Series
Basic UDI-DI:4719003MTT9

Digital Non-invasive Blood Pressure Monitors for Professional Use Series
Basic UDI-DI:4719003OBPDJ

Digital Peak Flow Meters Series
Basic UDI-DI:4719003PFSN

Digital Non-invasive Blood Pressure and Electrocardiogram Monitor Series
Basic UDI-DI: 4719003EBPBY

Class Im devices – MDN1207, MDS1010

Aneroid Sphygmomanometer Series
Basic UDI-DI: 4719003ANRR

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EU Quality Management System Certificate
TW23/00000625, continued

Microlife Corporation

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - TW/TPE/613065 - CTC
Authorized representative name and address (if relevant): Microlife UAB ; P. Lukšio g. 32 08222 Vilnius, Lithuania
Previous certificate number: N/A
Change in between this certificate and previous one: Add “Digital Non-invasive Blood Pressure and Electrocardiogram Monitor Series” to certificate scope

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EU Quality Management System Certificate
TW23/00000625, continued

Microlife Corporation

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Sites

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

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

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