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 Quality Management System certificate (Annex IX QMS)

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

This certificate is valid from 05 April 2024 until 24 August 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 24 February 2028

Issue 3. Certified since 24 August 2023
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager
SGS Belgium NV NB1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

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EU Quality Management System Certificate TW23/00000625, continued

Microlife Corporation

MDR EU Quality Management System certificate (Annex IX QMS)

Class IIa - MDA0203, MDS1010

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

Digital Non-invasive Blood Pressure Monitor for Home Use 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

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 1.11
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: Scope rewording and adding Digital Non-invasive Blood Pressure Monitors for Professional Use Series and Digital Peak Flow Meters Series

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EU Quality Management System Certificate TW23/00000625, continued

Microlife Corporation

MDR EU Quality Management System certificate (Annex IX QMS)

Issue 3

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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