DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

American Diagnostic Corporation
55 Commerce Drive
Hauppauge, New York, 11788
United States of America

23.05.2024

Notified Body Confirmation Letter

Reference: 31624353

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance 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, DQS Medizinprodukte GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 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:

American Diagnostic Corporation
55 Commerce Drive
Hauppauge, New York, 11788
United States of America

SRN Number (if available): US-MF-000021544

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided

evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

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 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 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)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 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,

Alexander Hohn
Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	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
Aneroid Sphygmomanometers, Sub-Group Clock Aneroid Sphygmomanometers, 750W Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Clock Aneroid Sphygmomanometers, 750D Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Clock Aneroid	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021

Device name or Basic UDI-DI (under MDR application)	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
Sphygmomanometers, 752M Series			POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 703 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 705 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 730 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 731 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 732 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Palm Aneroid Sphygmomanometers, 740 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 700 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 720 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 760 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434

Device name or Basic UDI-DI (under MDR application)	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
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 770 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 775 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 780 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 785 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434
Aneroid Sphygmomanometers, Sub-Group Pocket Aneroid Sphygmomanometers, 790 Series	Class I devices with a measuring function	Not applicable	1434-MDD-371/2021 POLISH CENTRE FOR TESTING AND CERTIFICATION, 1434

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
17.05.2024	31624353-1	Initial issue
23.05.2024	31624353-2	Moved devices from table 2 to table 1
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60148105 0001

Report No.: 10052841 014

Manufacturer:
K-jump Health Co., Ltd.
No. 56, Wu Kung 5th Rd.
New Taipei Industrial Park
New Taipei City, 24890
Taiwan

Products:
Medical Devices

(see attachment for products and sites included)

Replaces Approval, Registration No.: HD 60144083 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-07-28

Date: 2020-07-28

Notified Body

Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60148105 0001
Report No.: 10052841 014

Manufacturer:
K-jump Health Co., Ltd.
No. 56, Wu Kung 5th Rd.
New Taipei Industrial Park
New Taipei City, 24890
Taiwan

Products:

- Clinical Electronic Thermometers
- Infrared Thermometers (Ear & Forehead)
- Non-Invasive Electronic Sphygmomanometers (Blood Pressure Meters)
- Nebulizers
- Peak Flow Meters

Sites included:

K-jump Health Co., Ltd.
No. 56, Wu Kung 5th Road, New Taipei Industrial Park,
New Taipei City 24890, Taiwan

Dongguan Polygreen Technology Co., Ltd.
Room 101, Building 1, No.19, Tianxing Road,
Huangjiang Town, Dongguan City,
Guangdong Province, China

Notified Body

Date: 2020-07-28

Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Letter of Confirmation #2

03 May 2024

FI24/07185P0

Hetaida Technology Co., Ltd.
Room 801,802,803,804,901,2# Building Scientific Research Center,
Songhu Intelligent Valley, No.6 Minfu Road,
Liaobu Town, Dongguan City, Guangdong Province,
P.R.China

Notified Body Letter of Confirmation

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance 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 Fimko Ltd, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0598 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:

Hetaida Technology Co., Ltd.
Room 801,802,803,804,901,2# Building Scientific Research Center,
Songhu Intelligent Valley, No.6 Minfu Road,
Liaobu Town, Dongguan City, Guangdong Province,
P.R.China

SRN: CN-MF-000032793

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

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.c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 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)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 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,

Helsinki, 03 May 2024

Seppo Vahasalo, Notified Body Manager

SGS Fimko Ltd

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	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
Infrared Body Thermometer Model: HTD8818A, HTD8808C, HTD8816C, HTD8813, HTD8819, HTD8216C, HTD8222EU, HTD8219EU, HTD8823EU	Class IIa	N/A	FI17/07005, Issue 4 NB0598
Infrared Ear Thermometer Model: HTD8208C	Class IIa	N/A	FI17/07005, Issue 4 NB0598

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	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
N/A	N/A	N/A	N/A

EC Certificate Full Quality Assurance System FI17/07005

The management system of

Hetaida Technology Co., Ltd

Room 801, 802,803,804,901, 2# Building Scientific Research Center, Songhu Intelligent Valley, No.6 Minfu Road, Liaobu Town, Dongguan City, Guangdong Province, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II (excluding section 4)

For the following products

Infrared Body Thermometers
Infrared Ear Thermometers

Products covered and additional sites are listed in Attachment 1 of this certificate

This certificate is valid from 06 April 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 9 May 2017
This certification is based on decision: FI20/07030P0

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by

Jani Högman
Certifier

SGS Fimko Ltd., Notified Body 0598
Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

VALID TO 31th Dec. 2022
ONLY for HeTaiDa Thermometer sell. If it want to longer the valid time please contact seller.

Attachment 1 to SGS Fimko Ltd. EC certificate FI17/07005 Issue 4

Manufacturer	Hetaida Technology Co., Ltd	
Address	Room 801, 802,803,804,901, 2# Building Scientific Research Center, Songhu Inteligent Valley, No.6 Minfu Road, Liaobu Town, Dongguan City, Guangdong Province, P.R. China	
Other Addresses covered by the certificate	Location	Activity at the location
	Room 401,501,601, 2# Building, No.501,Dalingshan Section, Guanchang Road,Dalingshan Town, Dongguan City, Guangdong Province, P.R. China	Production, inspection, logistic,

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

Medical Device	Class	Model/type nr. and Trademark(s)
Infrared Body Thermometer	IIa	HTD8818A
Infrared Body Thermometer	IIa	HTD8808C
Infrared Body Thermometer	IIa	HTD8816C
Infrared Body Thermometer	IIa	HTD8813
Infrared Body Thermometer	IIa	HTD8819
Infrared Ear Thermometer	IIa	HTD8208C
Infrared Body Thermometer	IIa	HTD8216C
Infrared Body Thermometer	IIa	HTD8222EU
Infrared Body Thermometer	IIa	HTD8219EU
Infrared Body Thermometer	IIa	HTD8823EU

ONLY for HeTaiDa Thermometer with this mark. Contact seller to longer the valid time please

VALID TO 31th Dec. 2022

DECISION

06 April 2020 FI21/07030P0

Hetaida Technology Co. Ltd
Room 801, 802,803,804,901, 2# Building Scientific Research Center, Songhu Intelligent Valley, No.6 Minfu Road, Liaobu Town, Dongguan City, Guangdong Province,
P.R. China

EC-certification application 17/064-8, dated 2021-04-06

Subject

Certification amendment, due P.R. China address regulation change, based on Council Directive 93/42/EEC concerning medical devices, Annex II Section 3 (excluding Section 4). New addresses listed below.

Manufacturer

Manufacturer	Hetaida Technology Co. Ltd	
Address	Room 801, 802,803,804,901, 2# Building Scientific Research Center, Songhu Intelligent Valley, No.6 Minfu Road, Liaobu Town, Dongguan City,Guangdong Province, P.R. China	
Other Addresses covered by the certificate	Location	Activity at the location
	Room 401,501,601, 2# Building, No.501,Dalingshan Section, Guanchang Road,Dalingshan Town, Dongguan City, Guangdong Province, P.R. China	Production, inspection, logistics

Decision

A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	Model	Class
Infrared Body Thermometer	HTD6818A	IIa
Infrared Body Thermometer	HTD6808C	IIa
Infrared Body Thermometer	HTD6816C	IIa
Infrared Body Thermometer	HTD6813	IIa
Infrared Body Thermometer	HTD6819	IIa
Infrared Ear Thermometer	HTD6208C	IIa
Infrared Body Thermometer	HTD6216C	IIa
Infrared Body Thermometer	HTD6222EU	IIa
Infrared Body Thermometer	HTD6219EU	IIa
Infrared Body Thermometer	HTD6823EU	IIa

Justification

SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex II (excluding Section 4) of Medical Device Directive 93/42/EEC. The decision is based on Notification of Change, date 14 Jan 2014 and Physical address Conformance Statement, date 24 Feb 2021

The manufacturer has signed the undertaking to follow the obligations of Article II of the Directive 93/42/EEC.

VALID TO 31th Dec. 2022

Certificate related to decision

FI17/07005, Issue 4

Attachment to certificate

Attachment 1

Valid until

This decision is valid until 24 May.2024 providing the requirements of the certification are fulfilled.

Date

Helsinki, 06 April 2021

Jani Högman, Certifier
SGS Fimko Ltd, Notified Body 0598

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
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 1.6
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 amendment
This certificate is valid from 21 December 2023 until 24 August 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 24 February 2028
Issue 2. Certified since 24 August 2023

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

Date: 06th February 2024

SGS Reference Number: TW/TPE/613065

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

To whom it may concern

We hereby verify that the manufacturer Microlife Corporation, 9F, No. 431, RuiGuang Road, NeiHu, Taipei, 114, Taiwan, R.O.C. (SRN Number : TW-MF-000010688) possesses a MDR EU Quality Management System Certificate# TW23/00000625 (Issue 2. Certified since 24 August 2023), issued by SGS Belgium NV, Notified Body number 1639, confirming compliance with the requirements of the Medical Devices Regulation (EU) 2017/745.

Confirmation of Addresses
This is to confirm that both addresses listed below,
Address #1: 9F, N°431, RuiGuang Road, NeiHu, Taipei 114, Taiwan, R.O.C., and
Address #2: 9F, 431, RuiGuang Road, NeiHu, Taipei 11492, Taiwan, R.O.C.,
represent the same company certified by SGS Belgium NV.
Although there is a slight difference in the postal codes, both addresses indicate the location of Microlife Corporation. Either address indicated on the labeling or declaration of conformity is valid.

Confirmation of Models
The table provided below explicitly details the approved product models associated with SGS Certificate # TW23/00000625 corresponding to Microlife Corporation.

Approval of Conformity Certificate No. TW23/00000625			
Product Category and Basic UDI-DI	**Models (Commercial Product Name)**	**EMDN Code**	**GMDN Code**
Blood Pressure Long-term	[redacted]		

Approval of Conformity Certificate No. TW23/00000625			
Product Category and Basic UDI-DI	**Models (Commercial Product Name)**	**EMDN Code**	**GMDN Code**
Ambulatory Recorder Series Basic UDI-DI 4719003ABPBC	[redacted]		
Digital Non-invasive Blood Pressure Monitors for Home Use Series Basic UDI-DI 4719003HBPCF			

Approval of Conformity Certificate No. TW23/00000625			
Product Category and Basic UDI-DI	Models (Commercial Product Name)	EMDN Code	GMDN Code
	[redacted]		

Approval of Conformity Certificate No. TW23/00000625			
Product Category and Basic UDI-DI	Models (Commercial Product Name)	EMDN Code	GMDN Code
	[redacted]		
	BP3NU1-3P (BP3NU1-3P)	Z1203020501	45617
	[redacted]		
	BP3NZ1-3P (BP3NZ1-3P)	Z1203020501	45617
	[redacted]		
	BP3NZ1-H (BP3NZ1-H)	Z1203020501	47489
	[redacted]		
	BP3KF1-3B (BP3KF1-3B)	Z1203020501	45617
	[redacted]		

Approval of Conformity Certificate No. TW23/00000625			
Product Category and Basic UDI-DI	**Models (Commercial Product Name)**	**EMDN Code**	**GMDN Code**
Digital Infrared Thermometer series Basic UDI-DI 4719003IRSR	[redacted]		

Approval of Conformity Certificate No. TW23/00000625			
Product Category and Basic UDI-DI	Models (Commercial Product Name)	EMDN Code	GMDN Code
	[redacted]		
Digital Thermometer Series Basic UDI-DI 4719003MTT9			

Approval of Conformity Certificate No. TW23/00000625			
Product Category and Basic UDI-DI	**Models (Commercial Product Name)**	**EMDN Code**	**GMDN Code**
	[redacted]		
	MT3001 (MT3001)	V0301010201	14035
	[redacted]		
	MT1PF1 (MT1PF1)	V0301010201	14035
	[redacted]		
Digital Non-invasive Blood Pressure Monitors for Professional Use Series Basic UDI-DI 4719003OBPDJ	TWIN100 (TWIN100)	Z1203020501	45617
Digital Peak Flow Meter Series Basic UDI-DI 4719003PFSN	[redacted]		

The devices that fall within the scope of the certificate numbers and descriptors listed in the above table are considered to be in conformance with the requirements as per the issued certificate and are eligible for free sale within the European market.

The correlation in between Basic UDI-DI and commercial product name (Model N°) is established based on EU declarations established by the manufacturer Microlife Corporation.

Yours sincerely,

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