EC Certificate

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

Registration No.: HD 60149938 0001

Report No.: 15073607 023

Manufacturer:
Andon Health Co., Ltd.
No. 3 Jinping Street,
YaAn Road, Nankai District
Tianjin, 300190
P.R. China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60141761 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: 2020-06-29

Date: 2020-06-29

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60149938 0001
Report No.: 15073607 023

Manufacturer:
Andon Health Co., Ltd.
No. 3 Jinping Street,
YaAn Road, Nankai District
Tianjin, 300190
P.R. China

Ambulatory Blood Pressure Monitors, Electronic Sphygmomanometers, Electrical Muscle Stimulators, TENs Devices, Foetal Dopplers, Handheld Massagers, Rhinitis Retrievers, Blood Viscosity Therapeutic Equipments, Phototherapy Devices, Hypertension Treatment Devices, Portable ECG Monitors, Pulse Oximeters, Infrared Forehead Thermometers

Production site included:

Andon Medical Co., Ltd.
No.26 HangYu Road, Tianjin Airport Economic Area,
Tianjin 300380, China

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® III Zertifizierungsstelle III

Dipl.-Ing. W. Hsu

Date: 2020-06-29

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Andon Health Co., Ltd.
No.3 Jinping Street, YaAn Road, Nankai District,
300190 Tianjin,
P.R.China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date July 01, 2024

Notified Body Confirmation Letter
Reference. : ANDON_PLA0_2024-04-15, 2024-05-24; Order# 326030733

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 **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

Andon Health Co., Ltd.
No.3 Jinping Street, YaAn Road, Nankai District,
300190 Tianjin,
P.R.China
SRN Number (if available): CN-MF-000001799

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 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 May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either 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 March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

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:

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

Jason Pan

Jason Pan
Certification body

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**
Blood Pressure Monitor Basic UDI-DI: 69302518BPMD01GP	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPMD02GR	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPMD03GT	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPMD04GV	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPMD05GX	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197

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
Blood Pressure Monitor Basic UDI-DI: 69302518BPMD06GZ	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPMD07H3	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPWD01JV	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPWD02JX	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPWD03JZ	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPWD04K3	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPMI01HG	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPMI02HJ	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPWI01KN	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Blood Pressure Monitor Basic UDI-DI: 69302518BPWI02KQ	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Transcutaneous Electrical Nerve Stimulators (TENS Device)	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197

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
Basic UDI-DI: 69302518TENS04NY			
Pulse Oximeter Basic UDI-DI: 69302518PO0010CY	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Rhinitis Retrievers Basic UDI-DI: 69302518RR0011EV	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Infrared Forehead Thermometer Basic UDI-DI: 69302518IFT001EN	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Infrared Ear Thermometer Basic UDI-DI: 69302518IET001EB	Class IIa	N/A	Certificate #: DD 2095583-1 NB#: 0197
Clinical Digital Thermometer Basic UDI-DI: 69302518DT00019S	Class IIa	Digital Thermometer	Certificate #: DD 2095583-1 NB#: 0197
Portable ECG monitors Basic UDI-DI: 69302518ECG0089L	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197
Electrical Muscle Stimulators Basic UDI-DI: 69302518EMSYE	Class IIa	N/A	Certificate #: HD 60149938 0001 NB#: 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
None			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-07-01	ANDON_PLA0_2024-04-15, 2024-05-24; Order# 326030733	Initial issue