TÜVRheinland®

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2095583-1

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

Products: Blood Glucose Monitoring Systems Consisting of Blood Glucose Meters, Blood Glucose Test Strips and Control Solutions, Digital Pregnancy Tests, Digital Ovulation Tests, Digital Pregnancy and Digital Ovulation Tests, Pregnancy Test Strips, Ovulation Test Strips
Replaces Approval, Registration No.: HL 60144497 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC 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 IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 244412056-200

Effective date: 2022-05-21

Expiry date: 2025-05-26

Issue date: 2022-05-21

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

EC Certificate

Full Quality Assurance System
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Annex IV excluding (4, 6)

Registration No.: HL 2095583-1

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

The scope of certification includes the following manufacturing sites:

No.	Location
/01	Andon Medical Co ., Ltd. No.26 HangYu Road, Tianjin Airport Economic Area, 300380 Tianjin P.R. China

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Business Stream Products
Certification Department

TÜVRheinland®
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

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Mail: medical-products@de.tuv.com

Date June 02, 2025

Notified Body Confirmation Letter
Reference.: PDQ dated 2025-05-20; order # 326099610

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain in vitro diagnostic medical devices.

Only for Registration

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) 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 IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR 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 IVDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive 98/79/EC. Table 2 identifies the devices for which an IVDR 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 98/79/EC.

In the case of devices covered by certificates issued under Directive 98/79/EC (IVDD) that expired after May 26, 2022 and before July 9, 2024, without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under IVDR by the date of IVDD 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 54 of IVDR or Article 92 of the IVDR respectively, by July 9, 2024 for the relevant devices.

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Supervisory Board

Dr.-Ing. Michael Fübi

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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 110.3c of IVDR (as amended by (EU) 2024/1860), are shown below:

- 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR
- For devices not requiring the involvement of a notified body under the IVDD, but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:
    - 31 December 2027, for class D devices;
    - 31 December 2028, for class C devices;
    - 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition

On behalf of the Notified Body

Ning Chang

Ning N. C. Chang
Certification body

Only for Registration

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 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Blood Glucose Meters **Basic UDI-DI: 69302518BGM003AR**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Meters **Basic UDI-DI: 69302518BGM008B3**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Meters **Basic UDI-DI: 69302518BGM005AV**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Meters **Basic UDI-DI: 69302518BGM004AT**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Blood Glucose Meters **Basic UDI-DI: 69302518BGM009B5**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Meters **Basic UDI-DI: 69302518BGM010AN**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Meters **Basic UDI-DI: 69302518BGM006AX**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Meters **Basic UDI-DI: 69302518BGM007AZ**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Test Strips **Basic UDI-DI: 69302518BGS003C3**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Test Strips **Basic UDI-DI: 69302518BGS004C5**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Control Solutions **Basic UDI-DI: 69302518CS000396**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Control Solutions **Basic UDI-DI: 69302518CS000498**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Digital Pregnancy Test **Basic UDI-DI: 69302518DPT005GB**	B, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Digital Pregnancy Test **Basic UDI-DI: 69302518DPT006GD**	B, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Digital Ovulation Tests **Basic UDI-DI: 69302518DOT005FY**	B, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197

Only for Registration

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Digital Pregnancy and Digital Ovulation Tests **Basic UDI-DI: 69302518DPOT05LP**	B, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Pregnancy Test Strips **Basic UDI-DI: 69302518PS0005EK**	B, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Pregnancy Test Strips **Basic UDI-DI: 69302518PS0006EM**	B, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Ovulation Test Strips **Basic UDI-DI: 69302518OS0005E6**	B, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Ovulation Test Strips **Basic UDI-DI: 69302518OS0006E8**	B, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Monitoring System **Basic UDI-DI: 69302518BGMS03G3**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Monitoring System **Basic UDI-DI: 69302518BGMS08GD**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Monitoring System **Basic UDI-DI: 69302518BGMS05G7**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Monitoring System **Basic UDI-DI: 69302518BGMS04G5**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Monitoring System **Basic UDI-DI: 69302518BGMS09GF**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Monitoring System **Basic UDI-DI:**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197

Only for Registration

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
69302518BGMS10FY			
Blood Glucose Monitoring System **Basic UDI-DI: 69302518BGMS06G9**	C, self-testing	N/A	Certificate #HL 2095583-1. NB# 0197
Blood Glucose Monitoring System **Basic UDI-DI: 69302518BGMS07GB**	C, self-testing	N/A	Certificate #HL 2095583-1. 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 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
None	-	-	-

Only for Registration

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2025-06-02	ANDON_CL1860_2025-06-02	Initial issue