



TÜVRheinland®

## EC Certificate

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

Registration No.: HL 60144497 0001

Report No.: 15073607 021

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

**Products:** In Vitro Diagnostic Medical Devices for Self- testing  
(see attachment for products and additional site included)  
Replaces Approval, Registration No.: HL 60141764 0001

**Expiry Date:** 2024-05-27

The Notified Body hereby declares that the requirements of Annex IV, excluding section 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.

**Effective Date:** 2019-12-06

**Date:** 2019-12-06

Notified Body



Herbert Zhong

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HL 60144497 0001  
**Report No.:** 15073607 021

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

**Site included:**

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

**Date:** 2019-12-06

**Notified Body**

**Herbert Zhong**

