

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Assure Tech. (Hangzhou) Co., Ltd.**  
**Building 4, No. 1418-50, Moganshan Road**  
**Gongshu District**  
**Hangzhou**  
**310011 Zhejiang**  
**P.R. China**

has established and applies a quality management system for medical devices  
for the following scope:

**(see attachment for scope and additional site included)**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-04-15  
Certificate Registration No.: SX 60145063 0001  
An audit was performed. Report No.: 15047225 017  
This Certificate is valid until: 2023-02-24

Certification Body



Date 2020-04-15



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

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

**Attachment to  
Certificate**

**Registration No.:** SX 60145063 0001  
**Report No.:** 15047225 017

**Organization:** Assure Tech. (Hangzhou) Co., Ltd.  
Building 4, No. 1418-50, Moganshan Road  
Gongshu District  
Hangzhou  
310011 Zhejiang  
P.R. China

**Scope:** Design and Development, Manufacture and Distribution of  
In Vitro Diagnosis of Rapid Test of Fertility, Tumor  
Markers, Cardiac Markers, Drugs of Abuse and Infectious  
Disease, In Vitro Diagnostic Test Kits and Related  
Instruments for the field of Immune Diagnosis, Blood Glucose  
Monitoring Systems (Blood Glucose Meter, Test Strip), Blood  
Cholesterol Monitoring Systems (Blood Cholesterol Meter,  
Test Strip), Digital Pregnancy Tests

**Site included**

Assure Tech. (Hangzhou) Co., Ltd.  
Building 1, No. 1418-50, Moganshan Road,  
Gongshu District, Hangzhou, Zhejiang 310011 China

Manufacture of Blood Glucose Monitoring Systems (Blood  
Glucose Meter, Test Strip), Blood Cholesterol Monitoring  
Systems (Blood Cholesterol Meter, Test Strip),  
Digital Pregnancy Tests

**Certification Body**



**Date:** 2020-04-15



**Fuxiu Sheng**