

Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2074650-1

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, Drug
of Abuse and Infectious Disease, In Vitro Diagnostic Test Kit sand 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



The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244447453-200
Effective date: 2022-11-29
Expiry date: 2025-11-28
Issue date: 2022-11-29



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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The scope of certification also covers the following:

| No. | Facility | Scope |
|-----|---|--|
| /01 | c/o Assure Tech. (Hangzhou) Co., Ltd. Building 1, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang P.R. China | Manufacture of Blood Glucose Monitoring Systems (Blood Glucose Meter, Test Strip), Blood Cholesterol Monitoring Systems (Blood Cholesterol Meter, Test Strip), Digital Pregnancy Tests |
| /02 | c/o Assure Tech. (Hangzhou) Co., Ltd. 2-5 floor, No. 219 Guangzhushan Road, Dipu Street, Anji County, Huzhou, Zhejiang P.R. China | Manufacture of In Vitro Diagnosis of Rapid Test of Fertility, Tumor Markers, Cardiac Markers, Drug of Abuse and Infectious Disease |
| /03 | c/o Assure Tech. (Hangzhou) Co., Ltd. Floor 2-5, No. 66, Building 17, No.2723, Fuchunwan Avenue, Chunjiang Street, Fuyang District, Hangzhou, Zhejiang P.R. China | Manufacture of In Vitro Diagnosis of Rapid Test of Fertility, Tumor Markers, Cardiac Markers, Drug of Abuse and Infectious Disease |

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