

# ISO 13485 Certificate



Product Service

## Certificate

No. Q5 095123 0007 Rev. 03

**Holder of Certificate:** Hangzhou AllTest Biotech Co., Ltd.  
550#, Yin Hai Street  
Hangzhou Economic and Technological Development Area  
310018 Hangzhou  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** Hangzhou AllTest Biotech Co., Ltd.  
550#, Yin Hai Street, Hangzhou Economic and Technological  
Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF  
CHINA

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production and Distribution of In Vitro Diagnostic Kit for Obstetrics and Gynecology, Infectious Disease, Drug of Abuse, Vitamin, Special Protein, Oncology, Cardiology and Biochemistry, and Digital test for pregnancy and ovulation. Home use, Clinical Laboratory use and Near Patient In-vitro Diagnostic Devices and the related POCT analyzer.

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH20106401

**Valid from:** 2020-09-25

**Valid until:** 2023-09-24

**Date,** 2020-08-05

Christoph Dicks  
Head of Certification/Notified Body