



# Certificate

No. Q5 108123 0001 Rev. 00

**Holder of Certificate:** **Zhejiang Anji Saianfu Biotech Co., Ltd**

2nd Floor, No. 3 Factory  
No. 489 WenYun Road  
TangPu Industrial Park, Dipu Subdistrict  
Anji county  
313303 Huzhou City, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Zhejiang Anji Saianfu Biotech Co., Ltd  
2nd Floor, No. 3 Factory, No. 489 WenYun Road, TangPu  
Industrial Park, Dipu Subdistrict, Anji county, 313303 Huzhou City,  
Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development,  
Production and Distribution of  
In Vitro Diagnostic Reagents for Rapid Tests for  
Fertility,  
Drug of Abuse, Cardiac Diseases,  
Infectious Diseases, Oncology**

**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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 108123 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5 108123 0001 Rev. 00)

**Report No.:** SH20165601

**Valid from:** 2020-10-26

**Valid until:** 2023-10-25

**Date,** 2020-10-26

Christoph Dicks  
Head of Certification/Notified Body