



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