



Certificate

No. Q5 002596 0002 Rev. 01

Holder of Certificate: **Lansion Biotechnology Co., Ltd.**
No.2 Qiande Road, Science Park, Jiangning District
210000 Nanjing, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Lansion Biotechnology Co., Ltd.
No.2 Qiande Road, Science Park, Jiangning District, 210000
Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate.

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of
Dry Fluorescence Immunoassay Analyzer,
Dry Fluorescence Immunoassay test kit,
Coagulation Test Kit(Electrochemistry),
Handheld coagulation 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). 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 002596 0002 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_002596_0002_Rev_01)

Report No.: SH20126602
Valid from: 2021-04-12
Valid until: 2024-04-02



Date, 2021-04-12

Christoph Dicks
Head of Certification/Notified Body