



Product Service

Certificate

No. Q5 005021 0001 Rev. 03

Holder of Certificate: **Wuhan HealthCare
Biotechnology Co., Ltd.**

Building #8
Optics Valley Precision Medicine Industry Park Phase 1
#9 Gaokeyuan 3rd. Road
East Lake High-Tech Zone
430206 Wuhan City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution
of In Vitro Diagnostic Kits and Pretreatment
Reagents for Genetic Testing using Fast Fluorescence
In Situ Hybridization Probe and PCR method**

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 005021 0001 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_005021_0001_Rev.03)

Report No.: SH24136501

Valid from: 2024-12-10

Valid until: 2027-12-09

Date, 2024-12-06

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Wuhan HealthCare Biotechnology Co., Ltd.**
Building #8, Optics Valley Precision Medicine Industry Park Phase
1, #9 Gaokeyuan 3rd. Road, East Lake High-Tech Zone, 430206
Wuhan City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate