



Certificate

No. Q5 073028 0008 Rev. 02

Holder of Certificate: **Amoy Diagnostics Co., LTD.**
No. 39, Dingshan Road
Haicang District
361027 Xiamen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Amoy Diagnostics Co., LTD.
No. 39, Dingshan Road, Haicang District, 361027 Xiamen,
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Specimen Preparation Kits and In-vitro Diagnostic Kits for Cancer Biomarkers, Infectious Diseases based on Molecular Biological Technologies**

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 073028 0008 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_073028_0008_Rev._02)

Report No.: GZ2202001
Valid from: 2022-02-06
Valid until: 2025-02-05

Date, 2022-01-27



Christoph Dicks
Head of Certification/Notified Body