



Certificate

No. Q5 104467 0001 Rev. 00

Holder of Certificate: **Hangzhou Testsea Biotechnology Co., Ltd.**
3rd Floor, Building 6 north, No. 8-2 Keji Avenue
Yuhang District
311121 Hangzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Hangzhou Testsea Biotechnology Co., Ltd.
3rd Floor, Building 6 north, No. 8-2 Keji Avenue, Yuhang District,
311121 Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF
CHINA

Certification Mark:



Scope of Certificate: **Design, Development, Production and Distribution of In-Vitro Diagnostic Kits for Fertility, Drug of abuse and Infectious Diseases**

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). See also notes overleaf.

Report No.: SH19155901

Valid from: 2020-02-21

Valid until: 2023-02-20

Date, 2020-02-21

Christoph Dicks
Head of Certification/Notified Body

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ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT