



## 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