

Certificate CN25/00005667

The management system of

Hangzhou Testsea Biotechnology Co., Ltd.

No. 13-2 Guanshan Road, Yuhang District, 311115 Hangzhou, Zhejiang, China

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Design and manufacture of In-vitro diagnostic test kits used in the detection of drugs of abuse, pregnancy testing, transmissible agents.

This certificate is valid from 02 September 2025 until 19 August 2028 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 19 August 2025

L. Moran

Authorised by

Liz Moran

Business Manager

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



Certificate CN24/00005276

The quality management system of

Hangzhou Testsea Biotechnology Co., Ltd.

SGS

No. 13-2 Guanshan Road, Yuhang District, 311115 Hangzhou, Zhejiang, China
Facility number: F007379

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Canada: Medical Devices Regulations (SOR/98-282) Part 1 - General

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design and manufacture of In-vitro diagnostic test kits used in the detection of drugs of abuse, pregnancy testing, transmissible agents including professional use, home use, point of care in-vitro diagnostic medical devices.

This certificate is valid from Effective date 2025-09-02 until Expiry date 2028-08-19 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 2024-08-20

L. Henderson

Authorised by

Lynn Henderson

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



This document is an authentic electronic certificate for Client business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

