By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Hangzhou Laihe Biotech Co., Ltd.
Room 401-406, F1-3, Building 1
No.425 Miaohouwang Road, Xixing Street
Binjiang District, Hangzhou
Zhejiang
310051
China

Facility ID Number: F007873

Holds Certificate No: **MDSAP 817727**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development, manufacture and distribution of in-vitro diagnostic rapid test kits used in the detection of immune and autoimmune status, tumor and cardiac markers, drugs of abuse, fertility testing, sexually transmissible agents, transmissible agents and fluorescent immunoassay analyzers, including tests for home use.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-04-02 Effective Date: 2025-04-02 Expiry Date: 2028-04-01

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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