

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2069313-1
Certificate Holder: Hangzhou Laihe Biotech Co., Ltd.
Room 401-406, F1-3, Building 1,
No.425 Miaohouwang Road, Xixing Street,
Binjiang District, Hangzhou,
310051 Zhejiang
P.R. China

Scope: Design and Development, Manufacture and Distribution of in-vitro diagnostic rapid test kits used in the detection of autoimmune status, tumor markers, cardiac markers, drugs of abuse, fertility testing, immune status, sexually transmissible agents, transmissible agents including devices for home use and fluorescent immunoassay instruments

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 326002272-200
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