





Certificate No. Q5 095295 0001 Rev. 02

Holder of Certificate:

Sejoy Biomedical Co., Ltd.

Area C, Building 2, No. 365, Wuzhou Road Yuhang Economic Development Zone 311100 Hangzhou City, Zhejiang PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of In Vitro Diagnostic Reagents, Control Materials and Instruments for Clinical Chemistry, Immunochemistry (Immunology) and Infectious Diseases

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5-095295-0001_Rev.02

Report No.:

SH23167603

Valid from: Valid until: 2023-10-30 2026-10-29

Date,

2023-10-24

Christoph Dicks Head of Certification/Notified Body





Certificate

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Applied Standard(s):

ISO 13485:2016 (EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021) Medical devices - Quality management systems -Requirements for regulatory purposes

Facility(ies):

Sejoy Biomedical Co., Ltd.

Area C, Building 2, No. 365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate