





Certificate

No. Q5 048128 0076 Rev. 03

Holder of Certificate: Hangzhou Bioer Technology

Co., Ltd.

1192 BinAn Rd, Binjiang District

310053 Hangzhou

PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design, Development,

Production and Distribution of

Clinical Diagnostic Lab Instruments and In Vitro Diagnostic Reagents Based

on Molecular Biology Techniques

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:Q5-048128-0076-Rev.03

Report No.:

SH2209801

Valid from: Valid until:

2022-05-01 2025-04-30

C.DIL

Christoph Dicks

Head of Certification/Notified Body

Date,

2022-04-26





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Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Hangzhou Bioer Technology Co., Ltd.

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Design, Development, Production and Distribution of Clinical Diagnostic Lab Instruments and In Vitro Diagnostic Reagents Based on Molecular Biology Techniques

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