



America

CERTIFICATE

No. QS5 13 04 48128 043

Certificate Holder: Hangzhou Bioer Technology Co., Ltd.
1192BinAn Rd,Binjiang District
310053 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design, Production and Distribution of Real-Time PCR Detection System, Thermal Cycler, Dry Bath, Water Bath Series, Sample Preparing System, Gene-Lab, Incubator.

Standard(s): ISO 9001:2008

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: M6067

Effective Date: 2013-04-16

Expiry Date: 2016-04-15

Gary Minks
Vice President, Regulatory Affairs

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TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

TÜV®





Product Service

CERTIFICATE

No. Q1N 13 02 48128 050

Holder of Certificate: Hangzhou Bioer Technology Co., Ltd.

1192BinAn Rd, Binjiang District
310053 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Hangzhou Bioer Technology Co., Ltd.
1192BinAn Rd, Binjiang District, 310053 Hangzhou, PEOPLE'S
REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development,
Production and Distribution of
Clinical Diagnostic Lab Instruments
and In vitro Diagnostic Reagents Based
on Molecular Biology Techniques

**Applied
Standard(s):**

EN ISO13485:2012/AC:2012
ISO 13485:2003
Medical Devices - Quality Management Systems -
Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1309813

Valid from: 2013-05-01

Valid until: 2016-04-30

Date, 2013-04-02

Hans-Heiner Junker



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TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-999.98.12-46

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