



Certificate

No. Q5 092378 0007 Rev. 01

Holder of Certificate: **Healgen Scientific Limited
Liability Company**
3818 Fuqua Street
Houston TX 77047
USA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of
In Vitro Diagnostic Reagents for Cardiac Diseases,
Infectious Diseases, Oncology and for Biochemistry
as well as Rapid Tests for Fertility and Drugs of Abuse**

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 092378 0007 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_092378_0007_Rev.01)

Report No.: SH21178302

Valid from: 2022-02-09

Valid until: 2025-02-08

Date, 2022-02-09



Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 092378 0007 Rev. 01

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): **Healgen Scientific Limited Liability Company**
3818 Fuqua Street, Houston TX 77047, USA

Design and Development, Production and Distribution of
In Vitro Diagnostic Reagents for Cardiac Diseases,
Infectious Diseases, Oncology and for Biochemistry as well as
Rapid Tests for Fertility and Drugs of Abuse

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of
In Vitro Diagnostic Reagents for Cardiac Diseases,
Infectious Diseases, Oncology and for Biochemistry as well as
Rapid Tests for Fertility and Drugs of Abuse