



Product Service

# Certificate

No. Q5 089675 0005 Rev. 01

**Holder of Certificate:** **Beijing Hotgen Biotech Co.,Ltd**  
9th Building, No. 9 Tianfu Street, Biomedical Base  
Daxing District  
102600 Beijing  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** Beijing Hotgen Biotech Co.,Ltd  
9th Building, No. 9 Tianfu Street, Biomedical Base, Daxing District,  
102600 Beijing, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production, Distribution and Service of Automated Immunoassay Analyzer, Up-converting Phosphor Immunoassay Analyzer, Up-converting Phosphor Technology Test Kits, Colloidal Gold Test Kits, Chemiluminescence Immunoassay Test Kits, Enzyme-Linked Immunoassay Test Kits.

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)  
DIN EN ISO 13485:2016

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 089675 0005 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 089675 0005 Rev. 01)

**Report No.:** BJ20071201

**Valid from:** 2020-12-05

**Valid until:** 2023-12-04

**Date,** 2020-09-01

Christoph Dicks  
Head of Certification/Notified Body