



# Certificate

No. Q5 105113 0001 Rev. 04

**Holder of Certificate:** **Shenzhen New Industries Biomedical Engineering Co., Ltd.**  
No.23, Jinxiu East Road, Pingshan District  
518122 Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production, Distribution and Service of In Vitro Diagnostic Medical Devices (including Reagents, Analyzers, Quality Controls, Calibrators and Software) in the areas of Clinical Chemistry, Immunoassay and Molecular Diagnostic**

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\\_105113\\_0001\\_Rev.04](http://www.tuvsud.com/ps-cert?q=cert:Q5_105113_0001_Rev.04)

**Report No.:** GZ2313004-CN

**Valid from:** 2024-02-22

**Valid until:** 2025-12-31

**Date,** 2024-02-22



Christoph Dicks  
Head of Certification/Notified Body

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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):** **Shenzhen New Industries Biomedical Engineering Co., Ltd.**  
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen,  
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Distribution and Service of  
In Vitro Diagnostic Medical Devices including Clinical Chemistry  
Reagents, Immunoassay Reagents, Quality Controls, Calibrators,  
Software and Analyzers;  
Production and Distribution of In Vitro Diagnostic Medical Device  
for Molecular Diagnostic Reagents

**Shenzhen New Industries Biomedical Engineering Co., Ltd.**  
No.16, Jinhui Road, Pingshan District, 518122 Shenzhen,  
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production of In Vitro Diagnostic  
Medical Devices for Molecular Diagnostic Reagents;  
Production of In Vitro Diagnostic Medical Device including  
Analyzers and Immunoassay Reagents