



# Certificate

No. Q5 060578 0021 Rev. 02

**Holder of Certificate:** **InTec PRODUCTS, INC.**  
332 Xinguang Road  
Xinyang Industrial Area, Haicang  
361022 Xiamen, Fujian  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents and Instruments for Immunochemistry, Infectious Diseases, Clinical Chemistry, Immunohaematology (Blood Grouping)**

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 060578 0021 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 060578 0021 Rev. 02)

**Report No.:** SH2329603\_CN

**Valid from:** 2024-02-12

**Valid until:** 2024-07-30

**Date,** 2024-02-12

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):** **InTec PRODUCTS, INC.**  
332 Xinguang Road, Xinyang Industrial Area, Haicang, 361022  
Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution  
of In Vitro Diagnostic Reagents and Instruments for  
Immunochemistry, Infectious Diseases, Clinical  
Chemistry, Immunohaematology (Blood Grouping)

**InTec PRODUCTS, INC.**  
308-8 & 51 Wengjiao Road, Xinyang Industrial Area, Haicang,  
361022 Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production of  
In Vitro Diagnostic Reagents for  
Immunochemistry and Infectious Diseases