



# Certificate

No. Q5 060578 0021 Rev. 01

**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 Kits for Immunochemistry,  
Infectious Diseases, Clinical Chemistry,  
Haemostasis (Coagulation) and Related Instruments**

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. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_060578_0021_Rev.01)

**Report No.:** SH2129601

**Valid from:** 2021-07-31

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

**Date,** 2021-07-28

Christoph Dicks  
Head of Certification/Notified Body

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**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):**

**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 Kits for Immunochemistry,  
Infectious Diseases, Clinical Chemistry,  
Haemostasis (Coagulation) and Related Instruments

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

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and Infectious Diseases