



Certificate

No. Q5 060578 0021 Rev. 03

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, Certification, Validation and Verification Regulations 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. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_060578_0021_Rev.03)

Report No.: SH2429602

Valid from: 2024-07-31

Valid until: 2027-07-30

Date, 2024-07-22



Christoph Dicks

Head of Certification/Notified Body

Certificate

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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