



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.**
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Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA

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