





Product Service

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:



Design and Development, Scope of Certificate:

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

Report No.: SH2129601

Valid from: 2021-07-31 Valid until: 2024-07-30

Christoph Dicks Date. 2021-07-28

Head of Certification/Notified Body





Certificate

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EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

InTec PRODUCTS, INC. Facility(ies):

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

Design and Development,

Production of

In Vitro Diagnostic Kits for Immunochemistry,

and Infectious Diseases