



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4)
(List A)

No. V7 17 05 60578 019

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



EC-Representative: **Qarad b.v.b.a**
Cipalstraat 3
B-2440 GEEL
BELGIUM

Product: **Reagents for determination of infection markers
for HCV Rapid Tests**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. See also notes overleaf.

Report No.: 713089969

Valid from: 2017-11-10

Valid until: 2022-11-09



Date, 2017-11-10

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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(List A)**No. V7 17 05 60578 019****Model(s):** Diagnostic Kit for Antibody to
Hepatitis C Virus (Colloidal Gold)**Parameters:** **Model Name:**
Rapid Anti-HCV Test**Model No.:**
ITP01153-TC10, ITP01153-TC40,
ITP01152-TC25, ITP01152-TC40**Facility(ies):** InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Industrial Area,
Haicang, 361022 Xiamen, Fujian, PEOPLE'S
REPUBLIC OF CHINA

InTec PRODUCTS, INC.
308-8 Wengjiao Road, Xinyang Industrial Area,
Haicang, 361022 Xiamen, PEOPLE'S REPUBLIC OF
CHINA**Design
Facility(ies):** InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Industrial Area,
Haicang, 361022 Xiamen, Fujian, PEOPLE'S
REPUBLIC OF CHINA