



Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 060578 0025 Rev. 00

Manufacturer:

InTec PRODUCTS, INC.

332 Xinguang Road
Xinyang Industrial Area, Haicang
361022 Xiamen, Fujian
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement
is only valid in combination
with the following
EC Certificate (IVDD):

V7 060578 0022 Rev. 00

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (IVDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer
data initiated 26 May 2022 or later.

The conditions laid down in Article 110 (3) of Regulation (EU) 2017/746 on in vitro diagnostic
medical devices for placing devices on the market and putting into service apply. For details and
confirmation statement validity see: [www.tuvsud.com/ps-cert?q=cert:VCQ_060578 0025 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:VCQ_060578_0025_Rev_00)

Report No.:

SH2329603_CN_PRD

Valid until:

2024-09-03

Marta Carnielli
Head of Certification IVD

Issue Date: 2024-02-12



Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 060578 0025 Rev. 00

Product Category(ies): Reagents for determination of infection markers

for HCV Rapid Tests

Diagnostic Kit for Antibody to
Hepatitis C Virus (Colloidal Gold)

Model Name: Model No.:

Rapid Anti-HCV Test	ITP01152-TC25
Rapid Anti-HCV Test	ITP01152-TC40
Rapid Anti-HCV Test	ITP01153-TC10
Rapid Anti-HCV Test	ITP01153-TC40

Description of Change:

Change of Facility(ies): The facility(ies) of manufacturer has/have been changed

Old 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

New 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 & 51 Wengjiao Road, Xinyang Industrial Area,
Haicang, 361022 Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA



EC Certificate

EC Design-Examination Certificate

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

No. V7 060578 0022 Rev. 00

Manufacturer:

InTec PRODUCTS, INC.

332 Xinguang Road
Xinyang Industrial Area, Haicang
361022 Xiamen, Fujian
PEOPLE'S REPUBLIC OF CHINA

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. 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:V7_060578_0022_Rev.00

Report No.: 713234259

Valid from: 2022-04-11

Valid until: 2024-09-03

Date, 2022-04-11

Christoph Dicks
Head of Certification/Notified Body



EC Certificate

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

No. V7 060578 0022 Rev. 00

Model(s): **Diagnostic Kit for Antibody to
 Hepatitis C Virus (Colloidal Gold)**

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

Parameters:	Model Name:	Model No.:
	Rapid Anti-HCV Test	ITP01152-TC25
	Rapid Anti-HCV Test	ITP01152-TC40
	Rapid Anti-HCV Test	ITP01153-TC10
	Rapid Anti-HCV Test	ITP01153-TC40