



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 0024 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 0017 Rev. 01**

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\\_0024\\_Rev\\_00](http://www.tuvsud.com/ps-cert?q=cert:VCQ_060578_0024_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 0024 Rev. 00**

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

for HIV-1/ HIV-2: Anti-HIV-1/ HIV-2 Rapid Tests

ONE STEP Anti-HIV (1&2) Test

Model Name:

Model No.:

ONE STEP Anti-HIV (1&2) Test

ITP02152-TC25

ONE STEP Anti-HIV (1&2) Test

ITP02152-TC40

ONE STEP Anti-HIV (1&2) Test

ITP02153-TC40

ONE STEP Anti-HIV (1&2) Test

ITP02153-TC10

## 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 0017 Rev. 01**

**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 HIV-1/ HIV-2: Anti-HIV-1/ HIV-2 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 0017 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:V7_060578_0017_Rev.01)

**Report No.:** 713234264

**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 0017 Rev. 01**

**Model(s):** **ONE STEP Anti-HIV (1&2) Test**

**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

<b>Parameters:</b>	Model Name:	Model No.:
	ONE STEP Anti-HIV (1&2) Test	ITP02152-TC25
	ONE STEP Anti-HIV (1&2) Test	ITP02152-TC40
	ONE STEP Anti-HIV (1&2) Test	ITP02153-TC40
	ONE STEP Anti-HIV (1&2) Test	ITP02153-TC10