ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

Report No.: SH2129601

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

Date, 2021-07-28

Christoph Dicks
Head of Certification/Notified Body

MOLDOVA, ANENII NOI, RUSENI, SOCIETATEA CU RASPUNDERE LIMITATA MEDEFERENT GRUP - MEDEFERENT GRUP S.R.L.
IDNO 1002600053289
«MEDEFERENT GRUP»

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
TÜV®

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TÜV SÜD
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Certificate

No. Q5 060578 0021 Rev. 01

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.
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

IDNO 1002600053289
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DECLARATION OF CONFORMITY

Manufacturer	**InTec PRODUCTS, INC.** 332 Xinguang Road, Xinyang Industrial Area, Haicang, 361022, Xiamen, Fujian, P. R. China
Authorized Representative	**Qarad b.v.b.a** Cipalstraat 3, B-2440 Geel, Belgium
Product Name	Rapid Anti-HCV Test
Product Code	ITPW01152-TC25, ITPW01152-TC40, ITPW01153-TC40
CE Certificate	V10605780020 Rev.02 (valid until 2024-05-26)
Classification:	List A
Notified Body:	(NB 0123) TÜV SÜD Product Service GmbH TÜV SÜD Gruppe - Zertifizierstelle Ridlerstr. 65 – 80339 München Germany

Standards applied:

No.	Reference	Title of Harmonized Standard
01	EN ISO 13485: 2016	Medical device-Quality management systems-Requirements for regulatory purposes
02	EN ISO 14971:2012	Medical device-Application of risk management to medical devices
03	EN ISO 15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
04	EN 13612:2002	Performance evaluation of *in vitro* diagnostic medical devices
05	EN ISO 18113-1:2011	Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
06	EN ISO 18113-2:2011	Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
07	EN ISO 23640: 2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
08	EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
09	2009/886/EC	Common Technical Specifications for In Vitro Diagnostic Medical Devices
10	EN 62366:2008	Medical devices-Application of usability engineering to medical devices
11	REGULATION (EC) No 1272/2008	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
12*	EN ISO 11137-1:2015	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
13*	EN ISO 11137-2:2015	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
* Only applicable to accessory sterile disposable safety lancets; only ITPW01153-TC40 contains sterile disposable safety lancets.		

Add: 332 Xinguang Road, Xinyang Industry Area, Haicang
Xiamen
P. R. China

Tel: +86 592 6807188
Fax: +86 592 6519161
http://www.intecgsi.com

InTec PRODUCTS, INC.

Date: February 25, 2021
Lumin Jiao (Authorized Signatory)
General Manager
InTec PRODUCTS, INC. Place: Xiamen, China

Add: 332 Xinguang Road, Xinyang Industry Area, Haicang
Xiamen
P.R. China

Tel: +86 592 6807188
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http://www.intecasi.com

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 060578 0020 Rev. 02

Manufacturer:

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

Product Category(ies): **Screening test for Hepatitis C marker**
HIV markers and Products for self testing

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report no.: SH19296EXT01

Valid from: 2019-09-04
Valid until: 2024-05-26

Date, 2019-09-04

Stefan Preiß
Head of Certification/Notified Body

IDNO 1002600053289 «MEDEFERENT GRUP» S.R.L.

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 060578 0020 Rev. 02

Model(s):

ONE STEP Pregnancy Test (Test card for self-testing),
ONE STEP Pregnancy Test (Test strip for self-testing),
ONE STEP Pregnancy Test (Midstream test for self-testing),
ONE STEP Anti-HIV (1&2) Test,
Rapid Anti-HCV 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

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World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 3927
Fax direct: +41 22 791 4836
E-mail : diagnostics@who.int

In reply please refer to: CC vl

Your reference: P17-370-9

InTec PRODUCTS, INC
Attention: Mr Sean Lu
Quality Assurance Department
332, Xinguang Rd,
Xinyang Ind. Area, Haicang
Xiamen 361022
Chine (République populaire de)

17 May 2019

Dear Mr Lu,

Subject: **WHO Prequalification of In Vitro Diagnostics - Prequalification listing**

Product Name: Rapid Anti-HCV Test
Application Number: PQDx 0371-017-00

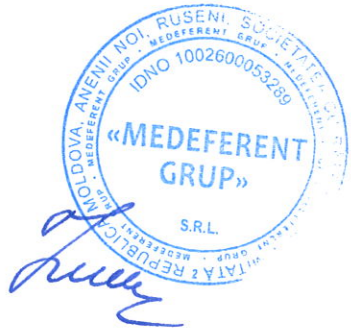
We are pleased to inform you that the above-referenced product was prequalified on 17 May 2019 and listed on the World Health Organization (WHO) list of prequalified in vitro diagnostic products.

The following post-prequalification activities are required to maintain the prequalification status:

1. Notification to WHO of any planned changes to a prequalified product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic*" (document number PQDx_121); and
2. Post-market surveillance activities, in accordance with "*WHO guidance on post-market surveillance of in vitro diagnostics*" (ISBN 978 92 4 150921 3).

You are also required to submit an annual report that details sales data and all categories of complaints in a summarized form. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents. The sales data will serve as denominator data to guide the frequency of re-inspection.

ENCL: as stated



Failure to comply with any of the above-mentioned post-prequalification requirements may lead to remedial action by WHO, including but not limited to, de-listing from the WHO list of prequalified in vitro diagnostic products.

If you have any questions, please do not hesitate to contact us by email (diagnostics@who.int) or by telephone (+4122 791 3927).

Yours sincerely,

Mr Deus Mabangizi
Coordinator
Prequalification Team
Regulation of Medicines and other Health Technologies

World Health Organization

WHO list of prequalified in vitro diagnostic products

RoW: Rest of the world. Regulatory version applied to products not approved by stringent/mature NRAs or not regulated

Last update: 27 May 2019

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2019	HIV RDT	ONE STEP Anti-HIV (1&2) Test	ITPW02152-TC40 ITPW02152-TC25 ITPW02153-TC40	rest-of-world	InTec PRODUCTS, INC	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	40 T/kit 25 T/kit 40 T/kit
2019	HCV RDT	Rapid Anti-HCV Test	ITPW01152-TC40; ITPW01152-TC25; and ITPW01153-TC40	rest-of-world	InTec PRODUCTS, INC	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	40 T/kit 25 T/kit 40 T/kit
2019	Malaria RDT	AdvDx Malaria Pf Rapid Malaria Ag Detection Test	00-DKM-RK-MALADX-004-025	rest-of-world	Advy Chemical Pvt Ltd.,	Plot No.A-334,336,338 & A-337 & 339 Road no. 25 & 26, Wagle industial Estate Thane 400 604 India	25 T/kit
2019	Malaria RDT	Alere Malaria Ag P.f	05FK140	CE-mark	Standard Diagnostics, Inc.	**site 1:** 46, Hagal-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea **site 2:** 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea	25T/Kit
			05FK141				25T/Kit
			05FK142				1T/kit x 25 each
			05FK143				1T/kit x 25 each
2019	HIV NAT	m-PIMA HIV-1/2 VL	27015-W50	rest-of-world	Alere Technologies GmbH	Loebstedter Str. 103-105, Jena, Thuringia, 07749, Germany	50 cartridges/kit
2018	Malaria RDT	First Response® Malaria Antigen P. *falciparum* (HRP2) Card Test	PI13FRC25s	rest-of-world	Premier Medical Corporation Limited	**site 1:** A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India; **site 2:** 32-35A, Shree Ganesh Industrial Estate, Kachigam, Nani Daman, Daman 396215, India	25 × single kit
			PI13FRC10s				10 × single kit
			PI13FRC25				25 × multi kit
			PI13FRC30				30 × multi kit
2018	Malaria RDT	First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC10s	rest-of-world	Premier Medical Corporation Limited	**site 1**: A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India; **site 2**: 32-35A, Shree Ganesh Industrial Estate,	10 × single kit
			PI16FRC25s				25 × single kit

InTec PRODUCTS

CERTIFICATE OF ANALYSIS

Component	RAPID ANTI-HCV TEST CARD
Format/Label	TC 40
Catalog Number	ITPW01153-TC40
Lot Number	GJ20080634
Date of manufacture	Aug, 2020
Expiration Date	Aug, 2022
Storage	2-30℃in Dry Condition
Physical Appearance	Conformed
Lot Size	24,600

QUALITY CONTROL DATA SHEET

Function Test	Specification	Result for this Lot (Pass/Fail)
Anti-HCV Negative	invisible line on TL area within 15 minutes	Pass
Anti-HCV Weak Positive	visible line on TL area within 5 minutes	Pass
Anti-HCV Medium Positive	visible line on TL area within 3 minutes	Pass
Anti-HCV Strong Positive	visible line on TL area within 1 minutes	Pass
Control Line	visible line on CL area within 2 minutes	Pass

Test Results: Passed

Date Released: Sep,01,2020

Operated by Qi Huang, Yan

Reviewed by Jin-feng, Zheng

INTEC PRODUCTS, INC XIAMEN

REPUBLICA MOLDOVA, ANENII NOI, RUSENI, SOCIETATEA MEDEFERENT GRUP, IDNO 1002600053289, «MEDEFERENT GRUP» S.R.L.