



InTec PRODUCTS, INC.

EU Declaration of Conformity

According to Annex III of 98/79/EC

We, InTec PRODUCTS, INC., with registered address at 332, Xinguang Road, Xinyang Industrial Area, Haicang 361022 Xiamen, Fujian, China, herewith declare that the below listed products meet the applicable provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices.

PRODUCT CODE	PRODUCT NAME
ITP16001-TC25	Rapid SARS-CoV-2 Antibody (IgG/IgM) Test
ITP16002-TC25	Rapid SARS-CoV-2 Antibody (IgG/IgM) Test
ITP16003-TC40	Rapid SARS-CoV-2 Antibody Test
ITP16004-TC40	Rapid SARS-CoV-2 Antibody Test

Technical documentation demonstrating compliance is kept at our registered address and can be made available by the authorized representative in Europe: QARAD b.v.b.a., Ciplastraat 3, B 2440 Geel, Belgium

Nicole Zhang

Nicole Zhang (Authorized Signatory)

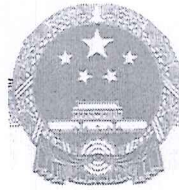
Director of Quality Center

InTec PRODUCTS, INC.

Place: Xiamen, China

Date: March 10, 2020

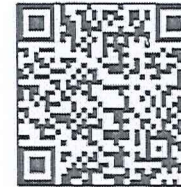




Unified Social Credit Code
91350200612005312M

Business License

(Duplicate)



For more information about registration, filing, and license supervision, scan the QR code to log in to the "National Enterprise Credit Information Publicity System".

Name INTEC PRODUCTS, INC(XIAMEN).

Corporate Type Legal Commercial Entity [Company Limited by Shares (Taiwan, Hong Kong, Macao Joint Venture with Domestic Investors), Unlisted]

Name of Legal Representative Jiao Lumin

Business Scope For inquiries related to business scope, place of business, investor information, annual report information, and regulatory information of the commercial entity, please refer to Xiamen Commercial Entity Registration and the Credit Information Publicity Platform. Business activities within the business scope subject to licensing approval shall not be carried out before obtaining approval from relevant departments.

Registered Capital CNY ONE HUNDRED AND FIFTY-SIX MILLION SEVENTY-ONE THOUSAND NINE HUNDRED AND NINETY-TWO ONLY

Date of Incorporation December 14, 1989

Term of Operation From December 14, 1989

Address No. 332 Xinguang Road, Xinyang Industrial Zone, Haicang, Xiamen

Registration Authority

Market Supervision
Administration of
Xiamen City
3502006117860
[seal]

June 27, 2019

Website of the National Enterprise Credit Information Publicity System: <http://www.gsxt.gov.cn>

The commercial entity shall disclose the annual report through Xiamen Commercial Entity Registration and the Credit Information Publicity Platform between January 1 and June 30 of each year.

Supervised by the State Administration for Market Regulation





Certificate

No. Q5 060578 0021 Rev. 00

Holder of Certificate: **InTec PRODUCTS, INC.**

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

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

Certification Mark:



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**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: SH1829614

Valid from: 2018-07-31

Valid until: 2021-07-30

Date, 2018-07-16

Stefan Preiß

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICATE ◆ CERTIFICATE

DECLARATION OF NOTIFICATION

Date: March 13, 2020

The undersigned, Sara Van Wouwe, Device Compliance Assistant of Qarad BVBA, hereby declares that:

InTec PRODUCTS, INC.
332, Xinguang Road, Xinyang Industrial Area
Haicang 361022 Xiamen, Fujian
China

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

Product name	Reference number
Rapid SARS-CoV-2 Antibody (IgG/IgM) Test	ITP16001-TC25
Rapid SARS-CoV-2 Antibody (IgG/IgM) Test	ITP16002-TC25
Rapid SARS-CoV-2 Antibody Test	ITP16003-TC40
Rapid SARS-CoV-2 Antibody Test	ITP16004-TC40

The notification to the Belgian Competent Authorities has been carried out on March 13, 2020 by Qarad BVBA the appointed Authorized Representative of InTec PRODUCTS, INC.

Information on the notification to the competent Authorities of other European countries is available upon request.

Sara Van Wouwe

Device Compliance Assistant

Qarad BVBA
Authorized Representative



Certificate of Approval

This is to certify that the Management System of:

Qarad BVBA

Cipalstraat 3, 2440 GEEL, Belgium

has been approved by LRQA to the following standards:

ISO 13485:2016



P.G. Cornelissen - Area Manager North Europe

Issued By: Lloyd's Register EMEA

for and on behalf of: Lloyd's Register Quality Assurance Limited

Current Issue Date: 14 September 2018

Expiry Date: 13 September 2021

Certificate Issue Number: 10107382

Original Approvals:

ISO 13485 – 14 September 2012

Approval Certificate Number: ISO 13485 – 0019831

The scope of this approval is applicable to:

The sales and provision of consulting, training, authorized representative services for IVD's and Medical devices and performance evaluations for IVD's. These services are also available from the Netherlands. The design and development, sales and provision of e-labeling services for the IVD and medical device industry.



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中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL
PRODUCTS

证书编号：闽厦药监械出 20200019 号

Certificate NO.: Min Xia Yao Jian Xie Chu No. 20200019

产品名称： 见附件

Product(s): See Attachment

规格型号： 见附件

Model: See Attachment

生产企业： 英科新创（厦门）科技股份有限公司

Manufacturer: InTec PRODUCTS, INC (XIAMEN).

生产企业住所： 厦门市海沧新阳工业区新光路 332 号

Address of manufacturer: 332 Xinguang Road, Xinyang Industrial Area,
Haicang, Xiamen, China

医疗器械出口备案凭证号： 见附件

Exportation Registration certificate(s): See Attachment

兹证明上述产品未在中国注册，尚未进入中国市场，该产品出口不受限制。

This is to certify that the above product(s) are not registered in China and not distributed on the Chinese market. The exportation of the product(s) is not restricted.

证明有效日期至： 2022 年 03 月 05 日

This certification is valid until: March 5, 2022

备注：

Remark:





英科新创（厦门）科技股份有限公司

存续（在营、开业、在册）

统一社会信用代码： 91350200612005312M

法定代表人： 焦鲁闽

登记机关： 厦门市市场监督管理局

成立日期： 1989年12月14日

发送报告

信息分享

信息打印

基础信息 | 行政许可信息 | 行政处罚信息 | 列入经营异常名录信息 | 列入严重违法失信企业名单（黑名单）信息

营业执照信息

- 统一社会信用代码： 91350200612005312M
- 类型： 股份有限公司(台港澳与境内合资、未上市)
- 注册资本： 15607.199200万人民币
- 营业期限自： 1989年12月14日
- 登记机关： 厦门市市场监督管理局
- 登记状态： 存续（在营、开业、在册）
- 住所： 厦门市海沧新阳工业区新光路332号
- 经营范围： 化学试剂和助剂制造（不含危险化学品和监控化学品及非药品类易制毒化学品）；其他未列明的机械与设备租赁（不含需经许可审批的项目）；医学研究和试验发展。（以上经营项目不含外商投资准入特别管理措施范围内的项目）

- 企业名称： 英科新创（厦门）科技股份有限公司
- 法定代表人： 焦鲁闽
- 成立日期： 1989年12月14日
- 营业期限至： 9999年12月31日
- 核准日期： 2019年06月27日

Business scope: Manufacturing of chemical reagents and auxiliaries (excluding hazardous chemicals, MCCs and non pharmaceutical precursor chemicals); leasing of other unlisted machinery and equipment (excluding items requiring government's approval); medical research and experimental development. (the above business items do not include those within the scope of Special Administrative Measures for foreign investment access)

发起人及出资信息

序号	发起人名称	发起人类型	证照/证件类型	证照/证件号码	详情
1	英科信实（厦门）投资合伙企业（有限合伙）	企业法人	企业法人营业执照(公司)		查看
2	INTEC HOLDINGS INTERNATIONAL LIMITED		非公示项	非公示项	查看

共 查询到 2 条记录 共 1 页

首页 | 上一页 | 1 | 下一页 | 末页

主要人员信息

共计 13 条信息

郭胜奇 监事	赖红梅 董事	沈立萍 董事	丁红 董事	SEAN WANG-LU 董事长	焦鲁闽 董事	焦鲁闽 总经理	黄金明 监事
黄敏	蔡宁 董事	JOHN GONG LU 董事	MICHAEL WA... 副董事长	刘小龙 董事			

分支机构信息

暂无分支机构信息

点击或下拉加载更多



营业执照

(副本)

统一社会信用代码

91350200612005312M



扫描二维码登录“
国家企业信用信息公示
系统”了解更
多登记、许可、备
案、监管信息

名称 英科新创（厦门）科技股份有限公司

注册资本 人民币 壹亿伍仟陆佰零柒万壹仟玖佰玖拾贰元整

类型 法人商事主体【股份有限公司(台港澳与境内合资、未上市)】

成立日期 1989年12月14日

法定代表人 焦鲁闽

营业期限 自1989年12月14日

经营范围

商事主体的经营范围、经营场所、投资人信息、年报信息和监管信息等请至厦门市商事主体登记及信用信息公示平台查询。经营范围中涉及许可审批经营项目的，应在取得有关部门的许可后方可经营。

住所 厦门市海沧新阳工业区新光路332号

登记机关



2019 年 06 月 27 日

CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

附件

Attachment

产品名称 Product Name	规格 Specification	医疗器械出口备案凭证号 Exportation Registration certificate(s)
新型冠状病毒抗体检测试剂（胶体金） Rapid SARS-CoV-2 Antibody Test	测试卡：10人份/盒, 20人份/盒, 25人份/盒, 40人份/盒; 测试条：50人份/盒, 100人份/盒; 1人份/袋 Test Card: 10T/Kit, 20T/Kit, 25T/Kit, 40T/Kit; Test Strip: 50T/Kit, 100T/Kit, 1 T/pouch;	闽厦 20200010
新型冠状病毒 IgM/IgG 抗体检测试剂 （胶体金） Rapid SARS-CoV-2 Antibody (IgM/IgG) Test	测试卡：10人份/盒, 20人份/盒, 25人份/盒, 40人份/盒; 测试条：50人份/盒, 100人份/盒; 1人份/袋 Test Card: 10T/Kit, 20T/Kit, 25T/Kit, 40T/Kit; Test Strip: 50T/Kit, 100T/Kit, 1 T/pouch;	闽厦 20200010
新型冠状病毒 IgM 抗体检测试剂（胶体金） Rapid SARS-CoV-2 Antibody (IgM) Test	测试卡：10人份/盒, 20人份/盒, 25人份/盒, 40人份/盒; 测试条：50人份/盒, 100人份/盒; 1人份/袋 Test Card: 10T/Kit, 20T/Kit, 25T/Kit, 40T/Kit; Test Strip: 50T/Kit, 100T/Kit, 1 T/pouch;	闽厦 20200010
新型冠状病毒 IgG 抗体检测试剂（胶体金） Rapid SARS-CoV-2 Antibody (IgG) Test	测试卡：10人份/盒, 20人份/盒, 25人份/盒, 40人份/盒; 测试条：50人份/盒, 100人份/盒; 1人份/袋 Test Card: 10T/Kit, 20T/Kit, 25T/Kit, 40T/Kit; Test Strip: 50T/Kit, 100T/Kit, 1 T/pouch;	闽厦 20200010



医疗器械生产许可证

许可证编号：闽食药监械生产许20100068号

企业名称：英科新创（厦门）科技股份有限公司

生产地址：

厦门市海沧新阳工业区新光路332号；厦门市海沧新阳工业区翁角路308号8号厂房

法定代表人：焦鲁闽

生产范围：

二类、三类6840体外诊断试剂；
二类6840临床检验分析仪器 ***

企业负责人：焦鲁闽

住 所：厦门市海沧新阳工业区新光路332号

发证部门：

福建省药品监督管理局



有效期限：至 2020 年 04 月 19 日

发证日期：

2019 年 06 月 28 日



营业执照

(副本)

统一社会信用代码
91350200612005312M



扫描二维码登录“国家企业信用信息公示系统”了解更多登记、许可、监管信息

名称 英科创新(厦门)科技股份有限公司

注册资本 人民币 壹亿伍仟陆佰零柒万壹仟玖佰玖拾贰元整

类型 法人商事主体【股份有限公司(台港澳与境内合资、未上市)】

成立日期 1989年12月14日

法定代表人 焦鲁闽

营业期限 自1989年12月14日

经营范围 商事主体的经营范围、经营场所、投资人信息、年报信息和监管信息等请至厦门市商事主体登记及信用信息公示平台查询。经营范围中涉及许可审批经营项目的，应在取得有关部门的许可后方可经营。

住所 厦门市海沧新阳工业区新光路332号

登记机关



2019年06月27日

Handwritten signature and date: 2019