

捷瑞泰
JR TYL

捷瑞泰额温枪出口资质

湖南省捷瑞泰医疗器械有限公司



对外贸易经营者备案登记表

备案登记表编号: 04746173

统一社会信用代码: 91430121083567239Q

进出口企业代码: _____

经营者中文名称	湖南省捷瑞泰医疗器械有限公司		
经营者英文名称	Hunan JRT Medical Devices Co.,Ltd		
组织机构代码	_____	经营者类型 (由备案登记机关填写)	有限责任公司
住 所	长沙经济技术开发区星沙产业基地蓝田北路梦工厂B5栋304		
经营场所 (中文)	长沙经济技术开发区星沙产业基地蓝田北路梦工厂B5栋304		
经营场所 (英文)	Room 304,building B5,dream factory,lantian north road,xingsha industry zone,changsha economic and technological development zone		
联系电话	0731-86791168	联系传真	0731-86791168
邮政编码	410000	电子邮箱	673726384@qq.com
工商登记注册日期	2013-11-21	工商登记注册号	_____

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	王羽丰	有效证件号	430426198009200036
注册资金	壹仟万元		(折美元)

依法办理工商登记的外国 (地区) 企业或个体工商户 (独资经营者) 还须填写以下内容

企业法定代表人 / 个体工商户负责人姓名		有效证件号	
企业资产 / 个人财产			(折美元)

备注	
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填表前请认真阅读背面的条款, 并由企业法定代表人或个体工商户负责人签字, 盖章。



2019 年 07 月 03 日

LST

Shenzhen LST Technology Co., Ltd.

HOTLINE: 400-096-8018

WWW.LST-LAB.COM

Certificate of Compliance

Certificate No. : LST200378039E-2
Applicant : Hunan JRT Medical Devices Co.,Ltd
Applicant Address : Room 304, Building B5, Dreamworks, No. 1, Lantian North Road, Xingsha Industrial Base, Changsha Economic and Technological Development Zone, Hunan Province, China
Manufacturer : Hunan JRT Medical Devices Co.,Ltd
Manufacturer Address : Room 304, Building B5, Dreamworks, No. 1, Lantian North Road, Xingsha Industrial Base, Changsha Economic and Technological Development Zone, Hunan Province, China
Product : Non-contact Infrared Thermometer
M/N : JRT-023
JRT-016, JRT-017, JRT-018, JRT-019, JRT-029
Trademark : JR TYL
Test Standard : EN 60601-1-2:2015
(CISPR 11:2015; IEC 61000-3-2:2014; IEC 61000-3-3:2013;
IEC 61000-4-2:2008; IEC 61000-4-3:2006; IEC 61000-4-4:2012;
IEC 61000-4-5:2014; IEC 61000-4-6:2013; IEC 61000-4-8:2009;
IEC 61000-4-11:2004)

The EUT described above has been tested by us with the listed standards and found in compliance with the council MDD directive 93/42/EEC. It is possible to use CE marking to demonstrate the compliance with this MDD Directive. It is only valid in connection with the test report number: LST200378039E-2.

CE



Manager

Issue Date: Apr. 07, 2020

Tel: +86 4000968018 Fax: +86 75529416623

4/F, Huichao Building, Yintian Industry zone, Bao'an District, Shenzhen China
www.lst-lab.com E-mail: lst_lab@126.com

LST

Shenzhen LST Technology Co., Ltd.

HOTLINE: 400-095-8018

WWW.LST-LAB.COM

Certificate of Compliance

Certificate No. : LST200378039F-2
Applicant : Hunan JRT Medical Devices Co.,Ltd
Applicant Address : Room 304, Building B5, Dreamworks, No. 1, Lantian North Road, Xingsha Industrial Base, Changsha Economic and Technological Development Zone, Hunan Province, China
Manufacturer : Hunan JRT Medical Devices Co.,Ltd
Manufacturer Address : Room 304, Building B5, Dreamworks, No. 1, Lantian North Road, Xingsha Industrial Base, Changsha Economic and Technological Development Zone, Hunan Province, China
Product : Non-contact Infrared Thermometer
M/N : JRT-023
JRT-016, JRT-017, JRT-018, JRT-019, JRT-029
Trademark : JR TYL
Test Standard :

The submitted sample of the equipment has been tested and found to comply with the following standards:

- FCC Part 15 B
- ANSI C63.4:2014

This verification is part of the full test report(s) and should be read in conjunction with it. The referred test report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified FCC standard. This Verification does not imply assessment of the production of the product. It is only valid in connection with the test report number: LST200378039FR-2.

FCC



Manager

Issue Date: Apr. 07, 2020

中华人民共和国医疗器械注册证

注册证编号：湘械注准20202070688

注册人名称	湖南省捷瑞泰医疗器械有限公司
注册人住所	湖南省长沙经济技术开发区星沙产业基地蓝田北路1号梦工厂B5栋304
生产地址	湖南省长沙经济技术开发区星沙产业基地蓝田北路1号梦工厂B5栋304
代理人名称	不适用
代理人住所	不适用
产品名称	非接触式红外体温计
型号、规格	JRT-016、JRT-017、JRT-018、JRT-019。
结构及组成	由红外传感器、信号接收处理器、按键、蜂鸣器、LCD显示和电池组成。
适用范围	通过测量额头的热辐射来显示被测对象的体温。
附件	产品技术要求
其他内容	
备注	该产品为应急审批注册。

审批部门：湖南省药品监督管理局

批准日期：2020年03月27日

有效期至：2025年03月26日



海关进出口货物收发货人备案回执

企业名称	湖南省捷瑞泰医疗器械有限公司
统一社会信用代码	91430121083567239Q
海关编码	430126084L
检验检疫备案号	4307600398
有效期	长 期



医疗器械生产许可证

湘食药监械生产许201900004号

许可证编号:

企业名称: 湖南省捷瑞泰医疗器械有限公司

生产地址: 湖南省长沙经济技术开发区星沙产业基地
蓝田北路1号梦工厂B5栋304

法定代表人: 王羽丰

生产范围: II类: 07-04 监护设备; 14-01 注射、穿刺器械;
18-02 妇产科测量、监护设; III类: - 旧版II
类: 无创监护仪器-6821-9 旧版III类: -

企业负责人: 王羽丰

住所: 湖南省长沙经济技术开发区星沙产业基地
蓝田北路1号梦工厂B5栋304

发证部门:



有效期限: 至 2024 年 02 月 04 日 发证日期: 2020 年 01 月 09 日

国家药品监督管理局制



营业执照

(副本)

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、
备案、许可、监
管信息。



副本编号：2 - 2

统一社会信用代码
91430121083567239Q

名称 湖南省捷瑞泰医疗器械有限公司

类型 有限责任公司(自然人投资或控股)

法定代表人 王羽丰

注册资本 壹仟万元整

成立日期 2013年11月21日

营业期限 2013年11月21日至 2043年11月20日

经营范围

一类医疗器械、二类医疗器械、三类医疗器械、计算机软件、计算机硬件、电子产品、二类医疗器械、一类医疗器械、三类医疗器械的研发；计算机硬件、医疗器械技术的开发；电子仪器、二类医疗器械、一类医疗器械、三类医疗器械的生产；软件零售；贸易代理；自营和代理各类商品及技术的进出口，但国家限定公司经营或禁止进出口的商品和技术除外。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

住所

湖南省长沙经济技术开发区星沙产业基地
蓝田北路1号梦工厂B5栋304

登记机关



2018年09月19日



Shenzhen POCE Technology Co.,Ltd.

H Building, Hongfa Science and Technology Park,
Tangtou, Shiyian, Bao'an District, Shenzhen, China

CERTIFICATE OF CONFORMITY

Certificate No. : POCE200428042RCE

Applicant : Hunan JRT Medical Devices Co., Ltd

Address : Room 304, Building B5, Dreamworks, No.1, Lantian North Road,
Xingsha Industrial Base, Changsha Economic and Technological
Development Zone, Hunan Province, China

Manufacturer : Hunan JRT Medical Devices Co., Ltd

Address : Room 304, Building B5, Dreamworks, No.1, Lantian North Road,
Xingsha Industrial Base, Changsha Economic and Technological
Development Zone, Hunan Province, China

Product : Forehead Infrared Thermometer

Trade Name : N/A

Model(s) : JRT-023, JRT-016, JRT-017, JRT-018, JRT-019, JRT-020, JRT-021,
JRT-022, JRT-029

Test Report No. : POCE200428041FRE

Test Standards : EN 55011:2016+A1:2017
EN 61326-1:2013
EN 61000-3-2:2019
EN 61000-3-3:2013+A1:2019

The EUT described above has been tested by us with the listed standards and found in compliance with the council EMC Directive 2014/30/EU. It is possible to use CE marking to demonstrate the compliance with this EMC Directive.




Jade Wang
For Chief Executive / Jade Wang
Date: Apr. 29, 2020

This certificate of conformity is based on a single evaluation of the submitted sample(s) of the above mentioned product. It does not imply an assessment of the whole production and other relevant directives have to be observed.



Web: <http://www.poce-cert.com> Tel: +86-755-29113252 E-mail: service@poce-cert.com



CERTIFICATION OF REGISTRATION

To:

Hunan Jrt Medical Devices Co., Ltd
Room 304, Building B5, Dreamworks, No.1, Lantian North Road, Xingsha
Industrial Base, changsha Economic and Technological Development Zone,
Changsha, Hunan, 410000, CHINA

is registered and has listed the following medical device with **the U.S. Food and Drug Administration(FDA)** :

Owner/Operator Number : 10070673

Listing Number: D393624

Product Code : FQZ

Product : Forehead Infrared Thermometer

Model(s) : JRT-018, JRT-016, JRT-017, JRT-023, CW-88

Date Of Registration Status: 2020

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by **the U.S. Food and Drug Administration(FDA)**. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration(FDA) does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with **the U.S. Food and Drug Administration(FDA)**



Chief Engineer / Zaccheo Lee

Issued: Apr. 18, 2020

Validity Period:2020-12-31



Establishment Registration & Device Listing Website :

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

JRT-018产品图



J R T-018包装尺寸



包装尺寸：

83mm*45mm*158mm

WELGHT:0.144KG



外箱尺寸：

576mm*338mm*449mm

120支/箱

WELGHT:18.58KG

JRT-018合格证

正面

— 产品保修卡 —		WARRANTY CARD																	
<p>1. 本保修卡请用户妥善保管，以备维修凭证。 2. 本产品自购买之日起保修2年。 3. 保修设备在保修期内，在正常使用和维护的情况下，机器本身机件材料及工艺出现问题，发生故障，经查明属实的，本公司将提供免费维修及更换零件。</p>		<p>1. Please keep this warranty card properly for maintenance certificate. 2. This product is guaranteed for 2 year from the date of purchase. 3. Warranty equipment During the warranty period, under normal use and maintenance, the machine parts materials and processes have problems and malfunctions. After verification, the company will provide free repairs and replacement parts.</p>																	
维修记录	<table border="1"><thead><tr><th>日期</th><th>故障原因及其处理情况</th></tr></thead><tbody><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr></tbody></table>	日期	故障原因及其处理情况							Maintenance records	<table border="1"><thead><tr><th>Date</th><th>Causes of failures and their handling</th></tr></thead><tbody><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr></tbody></table>	Date	Causes of failures and their handling						
日期	故障原因及其处理情况																		
Date	Causes of failures and their handling																		
客户名称		Customer name	Product model																
联系人		Contact person	Product Code																
联系电话		Contact number	Stamp																
客户地址		Customer address																	
产品名称		Product name																	
购买日期		Purchase date																	

尺寸:100mm

工艺:双折页

反面

— 合格证 —		QUALIFIED CERTIFICATE	
<p>品名:非接触式红外体温计 型号:JRT-018 规格:83mm*45mm*158mm 执行标准:GB 9706.1-2007 使用说明:通过测量额头的热辐射来显示被测对象的体温 检验员:005 检验标准:出厂检验合格 保质期:2年 生产日期:2020年4月23日 生产商:湖南省捷瑞泰医疗器械有限公司 生产批号:202004-WR 注册证编号:湘械注准20202070688 许可证编号:湘食药监械生产许20190004号 生产地址:湖南省长沙经济技术开发区星沙产业基地蓝田北路1号梦工厂B5栋304</p>		<p>Product name: Non-contact infrared thermometer Model: JRT-018 Specification: 83mm*45mm*158mm Executive standard: GB 9706.1-2007 Use instructions: measuring the thermal radiation of the forehead to display the temperature of the subject Inspector: 005 Inspection standard: factory inspection qualified Quality guarantee period: 2 year Production date: April 23, 2020 Manufacturer: Hunan Jieruitai Medical Devices Co., Ltd. Batch number: 202004-WR Registration certificate number: Xiang machinery injection standard 20202070688 Production license number: Hunan Food and Drug Supervision Equipment Production Xu No. 20190004 Production address: Room 304, Building B5, Dream Factory, No. 1 Lantian North Road, Xingsha Industrial Base, Changsha Economic and Technological Development Zone, Hunan Province</p>	
QC PASS		MADE IN CHINA	

JRT-019产品图



JRT-019包装尺寸



包装尺寸：

60mm*36mm*158mm

WELGHT:0.094KG



外箱尺寸：

498mm*392mm*274mm

120支/箱

WELGHT:12.48KG

JRT-019合格证

正面

— 产品保修卡 —		WARRANTY CARD	
<p>1. 本保修卡请用户妥善保管，以备维修凭证。 2. 本产品自购买之日起保修2年。 3. 保修设备在保修期内，在正常使用和维护的情况下，机器本身机件材料及工艺出现问题，发生故障，经查属实，本公司将提供免费维修及更换零件。</p>		<p>1. Please keep this warranty card properly for maintenance certificate. 2. This product is guaranteed for 2 year from the date of purchase. 3. Warranty equipment During the warranty period, under normal use and maintenance, the machine parts materials and processes have problems and malfunctions. After verification, the company will provide free repairs and replacement parts.</p>	
维修记录	日期	故障原因及其处理情况	
客户名称	产品型号		
联系人	出厂日期		
联系电话			
客户地址			
产品名称			
购买日期			

Maintenance records	Date	Causes of failures and their handling	
Customer name		Product model	
Contact person		Product Code	
Contact number		Stamp	
Customer address			
Product name			
Purchase date			



尺寸:100mm*63mm

工艺:双折页

反面

— 合格证 —		QUALIFIED CERTIFICATE	
<p>品名:非接触式红外体温计 型号:JRT-019 规格:57mm*34mm*157mm 执行标准:GB 9706.1-2007 使用说明:通过测量额头的热辐射来显示被测对象的体温 检验员:005 检验标准:出厂检验合格 保质期:2年 生产日期:2020年4月23日 生产商:湖南省捷瑞泰医疗器械有限公司 生产批号:202004-WR 注册证编号:湘械注准20202070688 许可证编号:湘食药监械生产许20190004号 生产地址:湖南省长沙经济技术开发区星沙产业基地蓝田北路1号梦工厂B5栋304</p>		<p>Product name: Non-contact infrared thermometer Model: JRT-019 Specification: 57mm*34mm*157mm Executive standard: GB 9706.1-2007 Use instructions: measuring the thermal radiation of the forehead to display the temperature of the subject Inspector: 005 Inspection standard: factory inspection qualified Quality guarantee period: 2 year Production date : April 23, 2020 Manufacturer:Hunan Jieruitai Medical Devices Co., Ltd. Batch number:202004-WR Registration certificate number: Xiang machinery injection standard 20202070688 Production license number: Hunan Food and Drug Supervision Equipment Production Xu No. 20190004 Production address: Room 304, Building B5, Dream Factory, No. 1 Lantian North Road, Xingsha Industrial Base, Changsha Economic and Technological Development Zone, Hunan Province</p>	



MADE IN CHINA

捷瑞泰生产一厂



捷瑞泰生产二厂

