孕橙

CE FDA CFDA

Shecare Smart Basal Thermometer

Bluetooth 4.0 Wireless Data synchronization High Accuracy:±0.05℃/0.09℉ Suitable both for Oral and Armp

AI Algorithm iOS/Android BLE SDK **Millions of products already manufactured No.1 Brand in China**

Brief Introduction of Shecare

Production Atlas

Environmental laboratory

Aging laboratory

Shecare （also named as Yuncheng）, located in Jiaxing City Zhejiang Province, is a high-tech medical enterprise integrating product manufacturing, R&D and marketing, committed to be one of the most professional IoT + AI cooperation in the field of home health in China.

Brief Introduction of Shecare

Since establishment, Shecare has been awarded many times. In the year of 2015,it won the silver medal of Tsinghua Principal‘s cup, interviewed by CCTV, and got the FDA in the same year； In 2017, it became the Class A program in “Innovation Jiaxing, Elite Leadership Program”, got CFDA and got IF of Smart Basalt Thermometer； In 2019 , it got the Gold Spectrum Award of Medical Device on China Brand Day； In 2020, its digital thermometer products got qualifications to go abroad like CE , FCC and NMPA, and become very popular globally at the same time.

Brief Introduction of Shecare

Nowadays, COVID-2019 has spread rapidly all over the world. Shecare, a medical company, is always full of courage to develop and dare to be first. With the shortage of anti-epidemic materials, Shecare together with its large numbers of outstanding engineers and R&D personnel, has successfully developed the all-new and non-contact infrared thermometers and portable digital thermometers rapidly, and set up a new production line to put into production, with a daily output of tens of thousands. The new production line adopts the top professional equipment, with complete production and assembly, which mast be efficient and satisfy the high demand for thermometers.

Business is warmly welcomed here.

Functions

Bluetooth Connection
Date automatically Uploaded to APP

High Accuracy： ±0.05℃/0.09℉

Functions

Suitable both for Oral cavity and Armpit

Stable Bluetooth Transmission

Functions

AI Algorithm

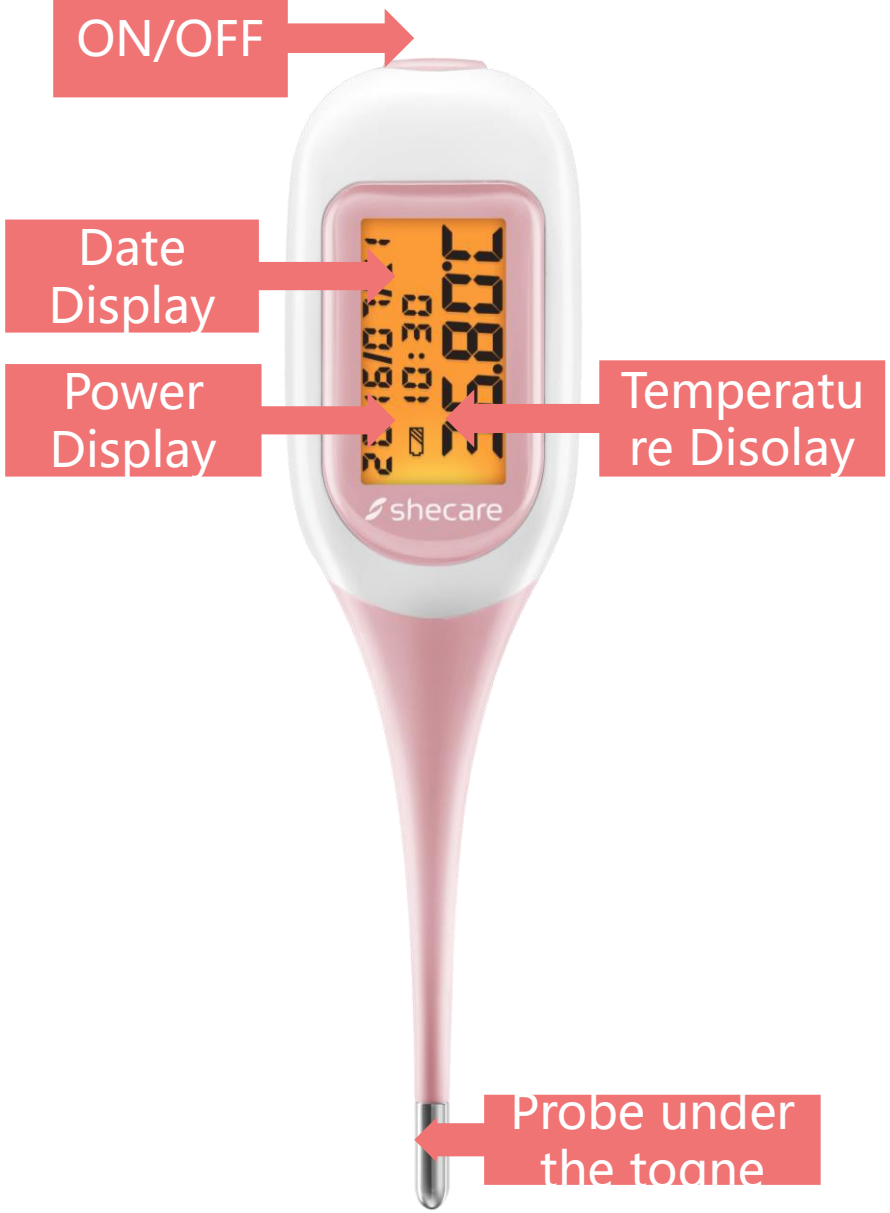
High Quality & elegant design

Product Parameters

Shecare Smart Basal Thermometer:

Mode	BT-A22B
Unite	°C/°F
Range	32.00°C - 42.99°C
Accuracy	±0.05°C (35.00°C - 38.00°C)
Measurement	3mins
Storage	5-40°C, Relative humidity≤ 85%
Battery Size	Button battery CR2032 （1pc）
Expiration	3years （battery unincluded）
Certificates	FDA CE CFDA

Functions



Date be automatically Uploaded to APP :when measurement finished, the date will be transmitted to Shecare APP automatically and then the app will generate the curve, no handnote or even turning-on the phone is needed.

High accuracy: the clinical accuracy is ±0.05℃/±0.09℉, the calibration temperature is 0.01℃/℉, in 3 mins the measurement will be done 。

Smart: The "CARE+" algorithm with completely independent intellectual property rights, combines multidimensional hormone time series analysis with deep learning and natural language technology on ovulation test.

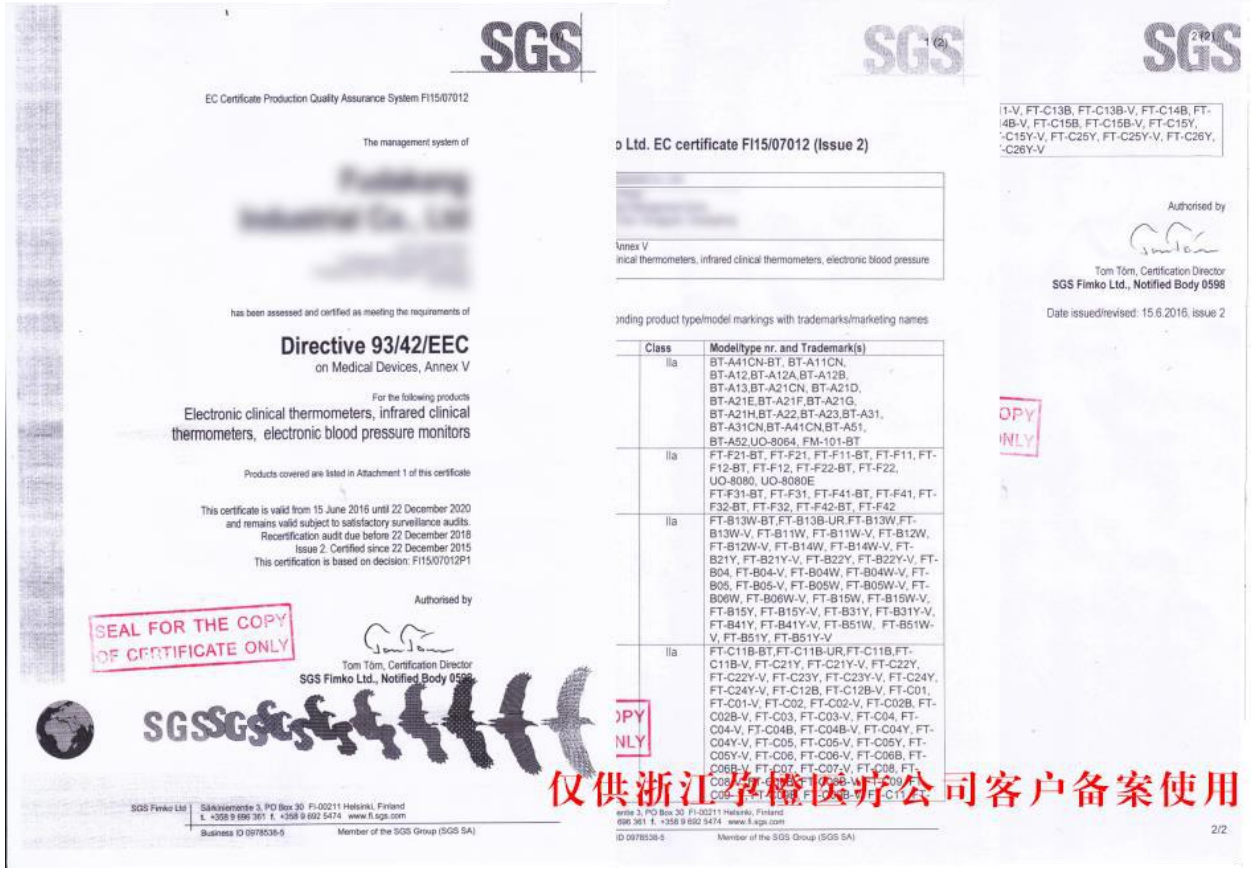
Backlit LCD Display: The result can be easily read even in the darkness.

400 groups of date storage: The shecare thermometer can store 400 groups of date, you can upload them every few days.

Multi-use, The thermometer can be multi-used for pre-pregancy, contrac period-management and fever-management

Product certification

Shecare Digital Thermometer：



SGS

EC Certificate Production Quality Assurance System FI15/07012

The management system of

[redacted]

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC
on Medical Devices, Annex V

For the following products
Electronic clinical thermometers, infrared clinical thermometers, electronic blood pressure monitors

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 15 June 2016 until 22 December 2020
and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 22 December 2018
Issue 2. Certified since 22 December 2015
This certification is based on decision: FI15/07012P1

Authorised by

Tom Törn, Certification Director
SGS Fimko Ltd., Notified Body 0598

SEAL FOR THE COPY OF CERTIFICATE ONLY

SGS Fimko Ltd | Särkiniementie 3, PO Box 30 FI-00211 Helsinki, Finland
t. +358 9 696 361 f. +358 9 692 5474 www.fi.sgs.com
Business ID 0978536-5 Member of the SGS Group (SGS SA)

SGS

Ltd. EC certificate FI15/07012 (Issue 2)

Annex V
inical thermometers, infrared clinical thermometers, electronic blood pressure

nding product type/model markings with trademarks/marketing names

Class	Model/type nr. and Trademark(s)
IIa	BT-A41CN-BT, BT-A11CN, BT-A12,BT-A12A,BT-A12B, BT-A13,BT-A21CN, BT-A21D, BT-A21E,BT-A21F,BT-A21G, BT-A21H,BT-A22,BT-A23,BT-A31, BT-A31CN,BT-A41CN,BT-A51, BT-A52,UO-8064, FM-101-BT
IIa	FT-F21-BT, FT-F21, FT-F11-BT, FT-F11, FT-F12-BT, FT-F12, FT-F22-BT, FT-F22, UO-8080, UO-8080E FT-F31-BT, FT-F31, FT-F41-BT, FT-F41, FT-F32-BT, FT-F32, FT-F42-BT, FT-F42
IIa	FT-B13W-BT,FT-B13B-UR,FT-B13W,FT-B13W-V, FT-B11W, FT-B11W-V, FT-B12W, FT-B12W-V, FT-B14W, FT-B14W-V, FT-B21Y, FT-B21Y-V, FT-B22Y, FT-B22Y-V, FT-B04, FT-B04-V, FT-B04W, FT-B04W-V, FT-B05, FT-B05-V, FT-B05W, FT-B05W-V, FT-B06W, FT-B06W-V, FT-B15W, FT-B15W-V, FT-B15Y, FT-B15Y-V, FT-B31Y, FT-B31Y-V, FT-B41Y, FT-B41Y-V, FT-B51W, FT-B51W-V, FT-B51Y, FT-B51Y-V
IIa	FT-C11B-BT,FT-C11B-UR,FT-C11B,FT-C11B-V, FT-C21Y, FT-C21Y-V, FT-C22Y, FT-C22Y-V, FT-C23Y, FT-C23Y-V, FT-C24Y, FT-C24Y-V, FT-C12B, FT-C12B-V, FT-C01, FT-C01-V, FT-C02, FT-C02-V, FT-C02B, FT-C02B-V, FT-C03, FT-C03-V, FT-C04, FT-C04-V, FT-C04B, FT-C04B-V, FT-C04Y, FT-C04Y-V, FT-C05, FT-C05-V, FT-C05Y, FT-C05Y-V, FT-C06, FT-C06-V, FT-C06B, FT-C06B-V, FT-C07, FT-C07-V, FT-C08, FT-

1-V, FT-C13B, FT-C13B-V, FT-C14B, FT-4B-V, FT-C15B, FT-C15B-V, FT-C15Y, -C15Y-V, FT-C25Y, FT-C25Y-V, FT-C26Y, -C26Y-V

Authorised by

Tom Törn, Certification Director
SGS Fimko Ltd., Notified Body 0598

Date issued/revised: 15.6.2016, issue 2

OPY
NLY

仅供浙江孕橙医疗公司客户备案使用

Member of the SGS Group (SGS SA)

2/2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 03 2010

Re: K101387
Trade/Device Name: Digital Thermometer, Models BT-A11CN, BT-A21CN, BT-A41CN
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 9, 2010
Received: July 19, 2010

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

quivalence determination does not
ice complies with other requirements
istered by other Federal agencies.
ding, but not limited to: registration
l); medical device reporting
CFR 803); good manufacturing
(QS) regulation (21 CFR Part 820);
l provisions (Sections 531-542 of

ling regulation (21 CFR Part 801),

CDRHOffices/ucm115809.htm for
H's) Office of Compliance. Also,
rence to premarket notification"
ting of adverse events under the

blem/default.htm for the CDRH's
narket Surveillance.

nsibilities under the Act from the
sumer Assistance at its toll-free
net address
ndustry/default.htm.

ours,

. Watson, B.S., M.S., M.B.A.

Anesthesiology, General Hospital,
Control and Dental Devices
levice Evaluation
Devices and
ical Health

ıs for Use

K101387

AUG 03 2010

surement and monitoring of
ospital or home.

llary measurement, oral

The-Counter Use ___X___
CFR 801 Subpart C)

N ANOTHER PAGE OF NEEDED)

Evaluation (ODE) 8/3/10

Page 1 of 1

esiology, General Hospital
Dental Devices

K101387

仅供浙江孕橙医疗公司客户备案使用

Company Qualification

统一社会信用代码
91330411MA28A74Y50 (1/1)

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

名　　称　浙江孕橙医疗科技有限公司

类　　型　有限责任公司（自然人投资或控股）

法定代表人　王胤

经营范围　一般项目：技术服务、技术开发、技术咨询、技术交流、技术转让、技术推广；第一类医疗器械销售；第一类医疗器械生产；第二类医疗器械销售；软件销售；软件开发；人工智能基础软件开发；计算机软硬件及辅助设备零售；计算机系统服务；电子产品销售(除依法须经批准的项目外，凭营业执照依法自主开展经营活动)。许可项目：第二类医疗器械生产；第三类医疗器械经营；食品经营；货物进出口(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，具体经营项目以审批结果为准)。

注册资本　壹仟万元整

成立日期　2016年01月29日

营业期限　2016年01月29日至长期

住　　所　浙江省嘉兴市秀洲区油车港镇正阳西路88号

登记机关　嘉兴市秀洲区市场监督管理局

2020年04月20日

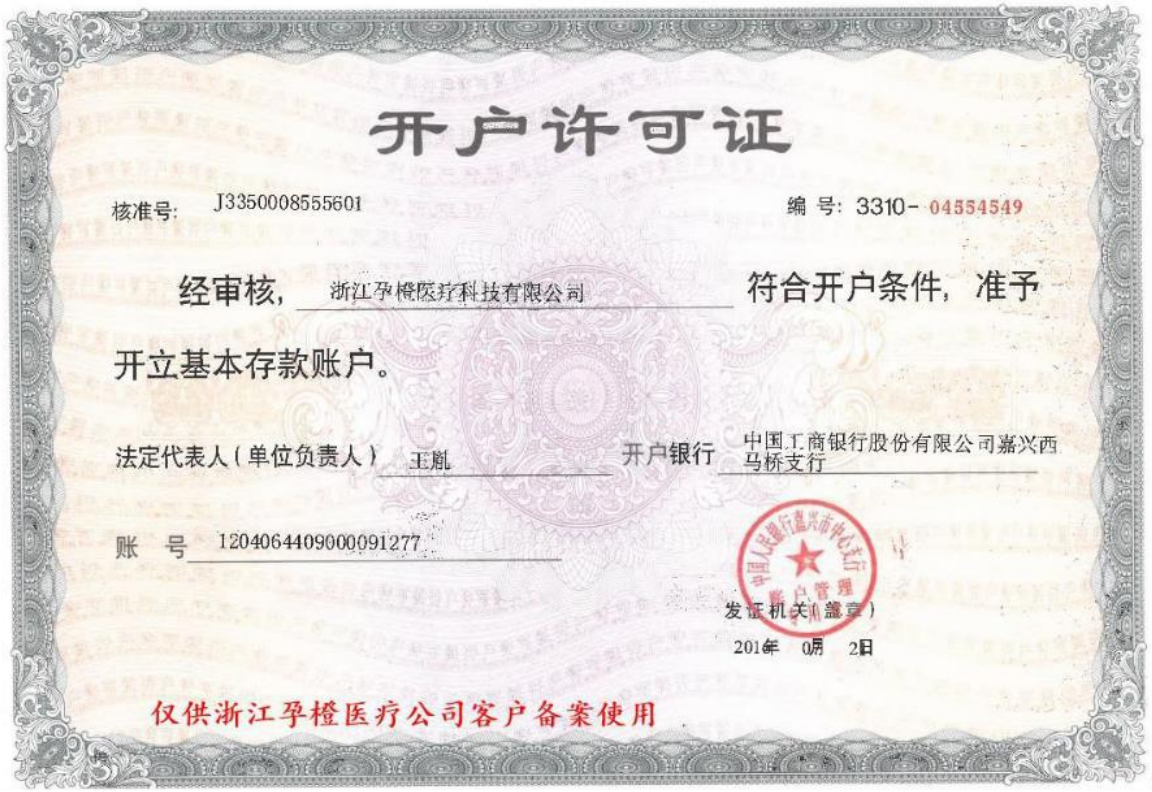
仅供浙江孕橙医疗公司客户备案使用

国家企业信用信息公示系统网址:http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家信用公示系统报送公示年度报告。

国家市场监督管理总局监制

Business License



开户许可证

核准号: J3350008555601

编号: 3310-04554549

经审核，浙江孕橙医疗科技有限公司符合开户条件，准予开立基本存款账户。

法定代表人（单位负责人）王胤

开户银行　中国工商银行股份有限公司嘉兴西马桥支行

账　号　1204064409000091277

发证机关(盖章)

2016年08月2日

仅供浙江孕橙医疗公司客户备案使用

Account Opening License

Company Qualification

医疗器械生产许可证

许可证编号：浙食药监械生产许20190061号

企业名称：浙江孕橙医疗科技有限公司

生产地址：浙江省嘉兴市秀洲区油车港镇正阳西路88号

法定代表人：王胤

生产范围：第Ⅱ类07-03生理参数分析测量设备***

企业负责人：王胤

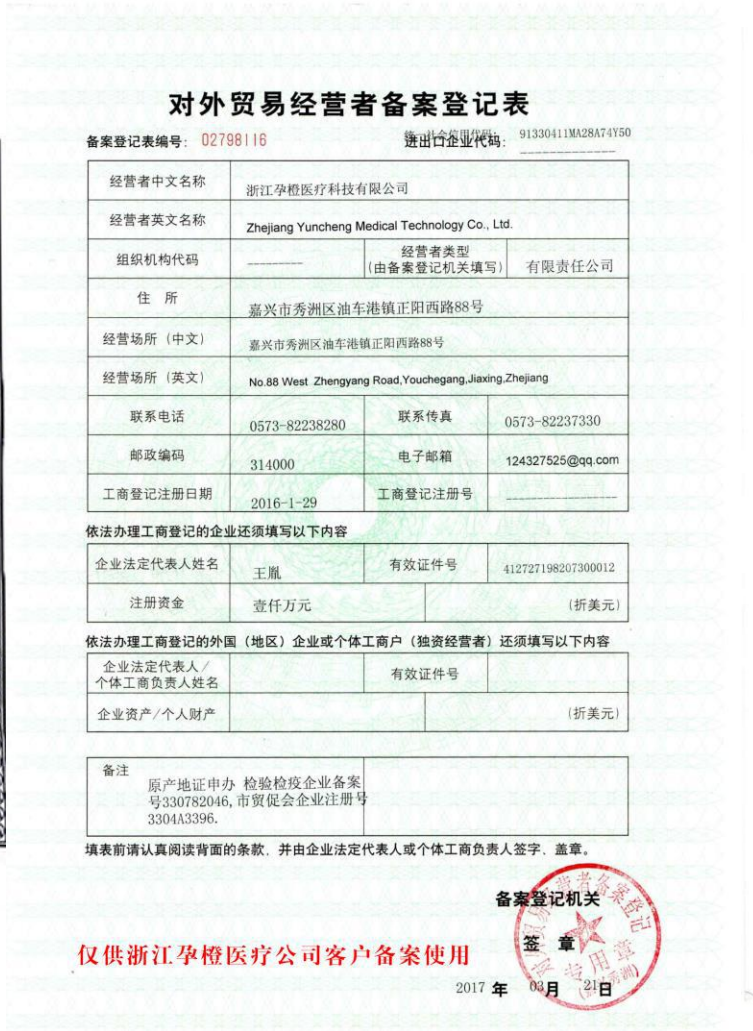
住　　所：浙江省嘉兴市秀洲区油车港镇正阳西路88号

发证部门：浙江省药品监督管理局

有效期限：至 2024年 10月 7日　　发证日期：2019年 10月 8日

国家食品药品监督管理总局制

Production License



对外贸易经营者备案登记表

备案登记表编号：02798116　　进出口企业代码：91330411MA28A74Y50

经营者中文名称	浙江孕橙医疗科技有限公司		
经营者英文名称	Zhejiang Yuncheng Medical Technology 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	嘉兴市秀洲区油车港镇正阳西路88号		
经营场所（中文）	嘉兴市秀洲区油车港镇正阳西路88号		
经营场所（英文）	No.88 West Zhengyang Road,Youchegang,Jiaxing,Zhejiang		
联系电话	0573-82238280	联系传真	0573-82237330
邮政编码	314000	电子邮箱	12432752S@qq.com
工商登记注册日期	2016-1-29	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	王胤	有效证件号	412727198207300012
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／个体工商负责人姓名		有效证件号	
企业资产／个人财产			（折美元）

备注	原产地证申办 检验检疫企业备案号330782046, 市贸促会企业注册号3304A3396.

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负责人签字、盖章。

备案登记机关

签　章

2017 年 03月 21日

Foreign Trade Registration Form

第二类医疗器械经营备案凭证

备案编号：浙嘉食药监械经营备20170420号

企业名称	浙江孕橙医疗科技有限公司
法定代表人	王胤
企业负责人	王胤
经营方式	批零兼营
住　　所	嘉兴市秀洲区油车港镇正阳西路88号
经营场所	嘉兴市秀洲区油车港镇正阳西路88号
库房地址	嘉兴市秀洲区油车港镇正阳西路88号
经营范围	（2002年分类目录）第II类医疗器械：6840体外诊断试剂，6813计划生育器械，6820普通诊察器械，6821医用电子仪器设备，6840临床检验分析仪器，6870软件***

备案部门（公章）

备案日期：2019年02月13日

Medical Device for Class II

Company Qualification

浙江孕橙开具增值税专用发票信息如下：

单位名称：浙江孕橙医疗科技有限公司

税号：91330411MA28A74Y50

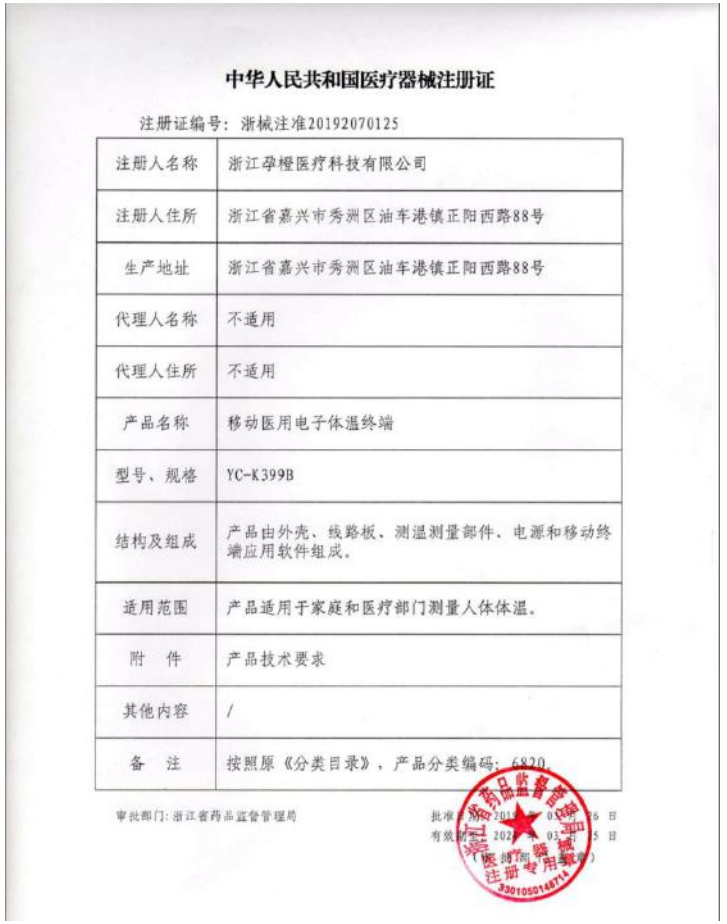
开户银行：中国工商银行股份有限公司嘉兴西马桥支行

1204064409000091277

地址及电话：嘉兴市秀洲区油车港镇正阳西路88号 0573-82618139

仅供浙江孕橙医疗公司客户备案使用

Invoice Infor



中华人民共和国医疗器械注册证

注册证编号：浙械注准20192070125

注册人名称	浙江孕橙医疗科技有限公司
注册人住所	浙江省嘉兴市秀洲区油车港镇正阳西路88号
生产地址	浙江省嘉兴市秀洲区油车港镇正阳西路88号
代理人名称	不适用
代理人住所	不适用
产品名称	移动医用电子体温终端
型号、规格	YC-K399B
结构及组成	产品由外壳、线路板、测温测量部件、电源和移动终端应用软件组成。
适用范围	产品适用于家庭和医疗部门测量人体体温。
附　件	产品技术要求
其他内容	/
备　注	按照原《分类目录》，产品分类编码：6820

审批部门：浙江省药品监督管理局

Medical Device Registration

中国农业银行账户　　美元账户

帐号：19300414040013039

户名：浙江孕橙医疗科技有限公司

开户行：中国农业银行嘉兴市分行国际部

币种：美元

账户性质：外汇帐户

Receiving US Dollar at Agricultural Bank of China

中国农业银行美元汇款路线指引

温馨提示：汇款人应将完整、准确的汇款路线告知境外汇出银行，以确保收款人及时收到款项。

Notice: Receiving U.S. Dollar in China can be easy and simple. Please request the remitter to instruct his/her bank to use the following payment route.

美元 汇款指示　USD payment instruction

56:U S intermediary Bank(中间行)；

Deutsche Bank Trust Company　Americas, NEW YORK.United States of America,SWIFT BIC:BKTRUS33

57:Account with institution(收款行)

Agricultural Bank of China.Head Office SWIFT BIC :ABOCCNBJ

59：Beneficiary(收款人)：

Account Number:（账户号码）

19300414040013039

仅供浙江孕橙医疗公司客户备案使用

Bank account of ABC