生产企业营业执照

统一社会信用代码

91620702MA7303GU8G

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	张掖市诺安医疗器械有限公司	注册资本	叁仟万元整
类　　型	有限责任公司(自然人投资或控股)	成立日期	2020年02月18日
法定代表人	江东	营业期限	长期
经营范围	医疗仪器设备及器械加工制造及销售；医疗设备销售、租赁；医疗用品及器材批发零售；基层医疗卫生服务；日用百货、针纺织品、家用电器、电子产品、保健食品批发零售；医疗器械及技术开发、技术转让及技术信息咨询；货物及技术进出口贸易。【依法需经批准的项目，经相关部门批准后方可开展经营活动】*	住　　所	甘肃省张掖市甘州区滨河新区智能终端产业园A区2号楼

登记机关

甘州区市场监督管理局

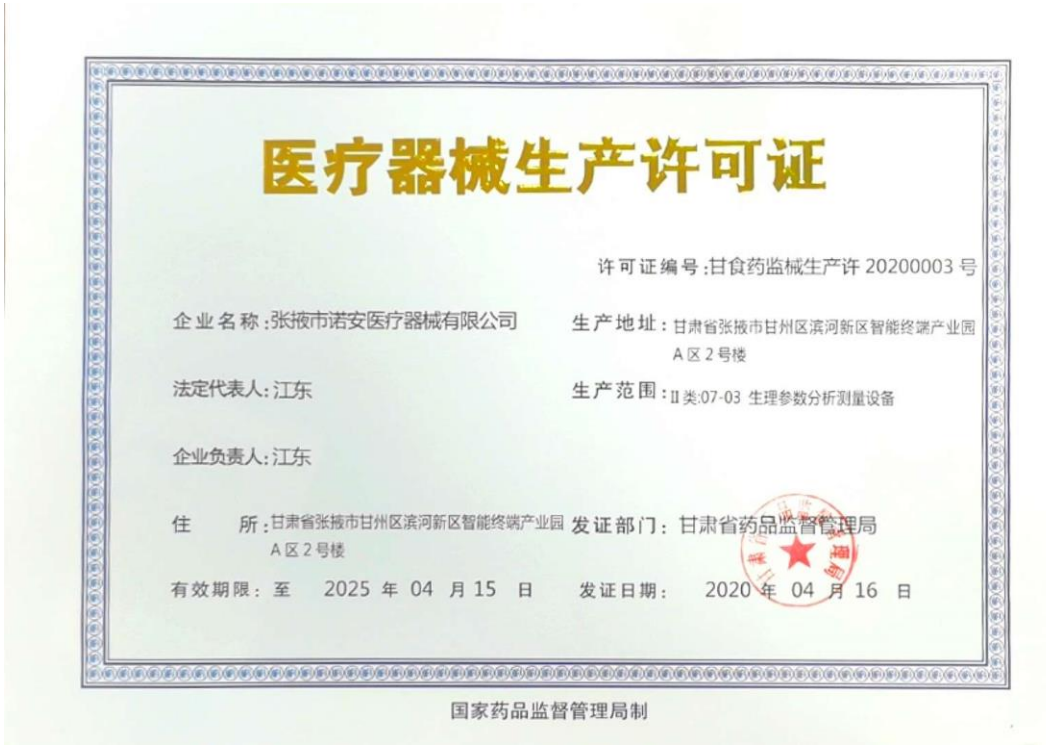
2020 年 03 月 23 日

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日通过国家企业信用信息公示系统报送公示年度报告

国家市场监督管理总局监制

医疗器械生产许可证



医疗器械生产许可证

许可证编号：甘食药监械生产许 20200003 号

企业名称：张掖市诺安医疗器械有限公司

生产地址：甘肃省张掖市甘州区滨河新区智能终端产业园A区2号楼

法定代表人：江东

生产范围：Ⅱ类:07-03 生理参数分析测量设备

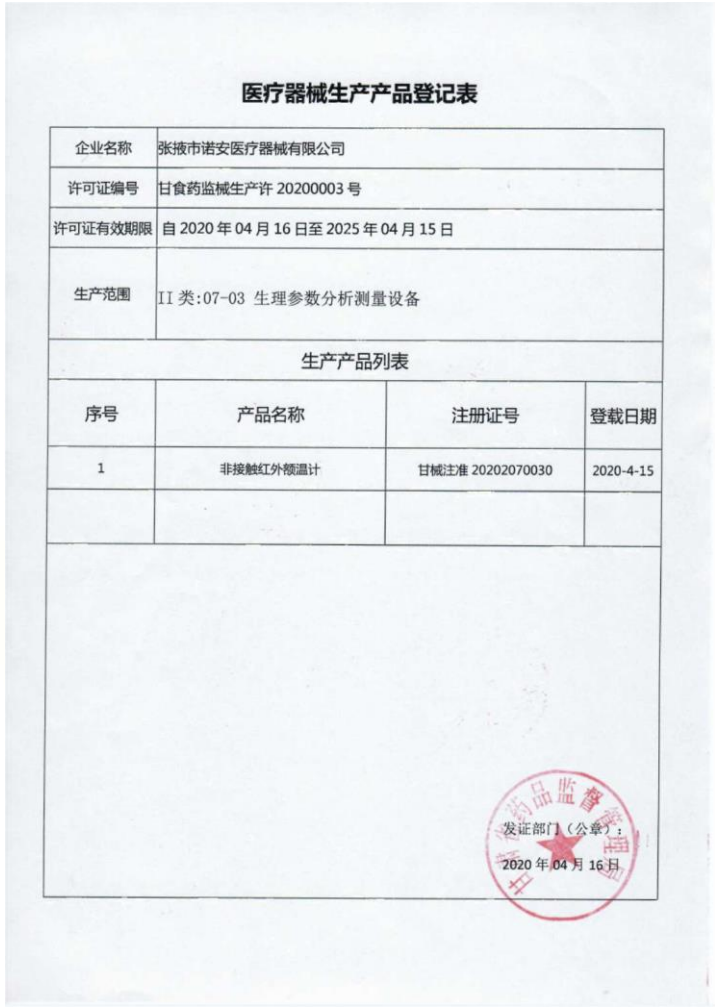
企业负责人：江东

住　　所：甘肃省张掖市甘州区滨河新区智能终端产业园A区2号楼

发证部门：甘肃省药品监督管理局

有效期限：至　2025 年 04 月 15 日　　发证日期：2020 年 04 月 16 日

国家药品监督管理局制



医疗器械生产产品登记表

企业名称	张掖市诺安医疗器械有限公司
许可证编号	甘食药监械生产许 20200003 号
许可证有效期限	自 2020 年 04 月 16 日至 2025 年 04 月 15 日
生产范围	II 类:07-03 生理参数分析测量设备

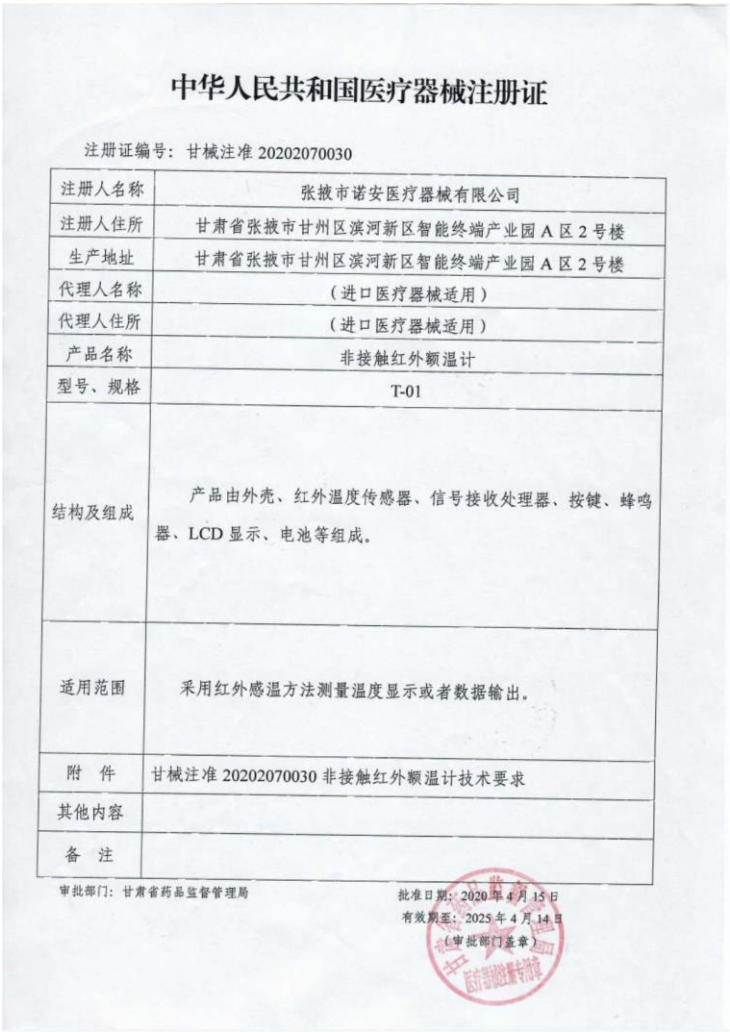
生产产品列表

序号	产品名称	注册证号	登载日期
1	非接触红外额温计	甘械注准 20202070030	2020-4-15

发证部门（公章）：

2020 年 04 月 16 日

医疗器械注册证



中华人民共和国医疗器械注册证

注册证编号：甘械注准 20202070030

注册人名称	张掖市诺安医疗器械有限公司
注册人住所	甘肃省张掖市甘州区滨河新区智能终端产业园 A 区 2 号楼
生产地址	甘肃省张掖市甘州区滨河新区智能终端产业园 A 区 2 号楼
代理人名称	（进口医疗器械适用）
代理人住所	（进口医疗器械适用）
产品名称	非接触红外额温计
型号、规格	T-01
结构及组成	产品由外壳、红外温度传感器、信号接收处理器、按键、蜂鸣器、LCD 显示、电池等组成。
适用范围	采用红外感温方法测量温度显示或者数据输出。
附　件	甘械注准 20202070030 非接触红外额温计技术要求
其他内容	
备　注	

审批部门：甘肃省药品监督管理局　　批准日期：2020 年 4 月 15 日
有效期至：2025 年 4 月 14 日
（审批部门盖章）

注册号查询步骤：

登陆

中国政府网 www.nmpa.gov.cn/WS04/CL2042/

点击

我国相关医疗器械产品注册信息

点击

国产红外体温计注册信息

查询



省级药监部门红外体温计（含耳温计、额温枪）注册信息

序号	注册证号	产品名称	注册人
1	川械注准20182070132	红外线额温枪	四川恒明科技开发有限公司
2	川械注准20202070020	红外体温计	四川优可得医疗器械有限公司
3	鄂械注准20172202329	红外体温计	武汉璟泓科技股份有限公司
4	鄂械注准20202072909	红外额温仪	湖北优迪欧光电科技有限公司
5	甘械注准20202070030	非接触红外额温计	张掖市诺安医疗器械有限公司
6	赣械注准20152200240	红外线电子体温计	江西安姆特母婴用品有限公司

厂家省级检测合格报告



160008222171

中国认可
国际互认
检测
TESTING
CNAS L0095

共 38 页 第 1 页

No. WTS2020-2164-1

检 测 报 告

TEST REPORT

产品名称：
NAME OF SAMPLE 非接触红外额温计

受检单位：
CLIENT 张掖市诺安医疗器械有限公司

检测类别：
CLASSIFICATION OF TEST 委托检测

威凯检测技术有限公司
Vkan Certification & Testing Co., Ltd.



共 12 页 第 1 页

No. WTS2020-2164-2

检 测 报 告

TEST REPORT

产品名称：
NAME OF SAMPLE 非接触红外额温计

受检单位：
CLIENT 张掖市诺安医疗器械有限公司

检测类别：
CLASSIFICATION OF TEST 委托检测

威凯检测技术有限公司
Vkan Certification & Testing Co., Ltd.



160008222171

中国认可
国际互认
检测
TESTING
CNAS L0095

共 24 页第 1 页

No. WTS2020-2164-3

检 测 报 告

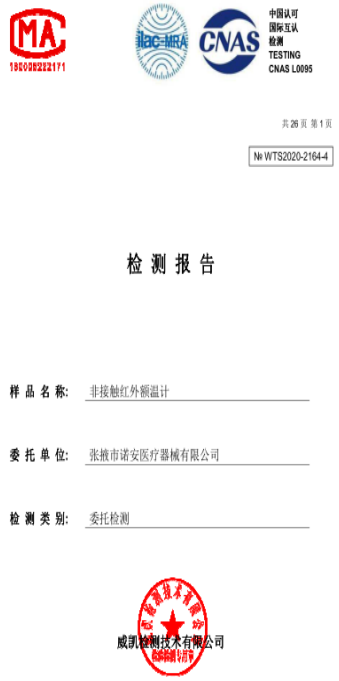
TEST REPORT

产品名称：
NAME OF SAMPLE 非接触红外额温计

受检单位：
CLIENT 张掖市诺安医疗器械有限公司

检测类别：
CLASSIFICATION OF TEST 委托检测

威凯检测技术有限公司
Vkan Certification & Testing Co., Ltd.



160008222171

中国认可
国际互认
检测
TESTING
CNAS L0095

共 26 页 第 1 页

№ WTS2020-2164-4

检 测 报 告

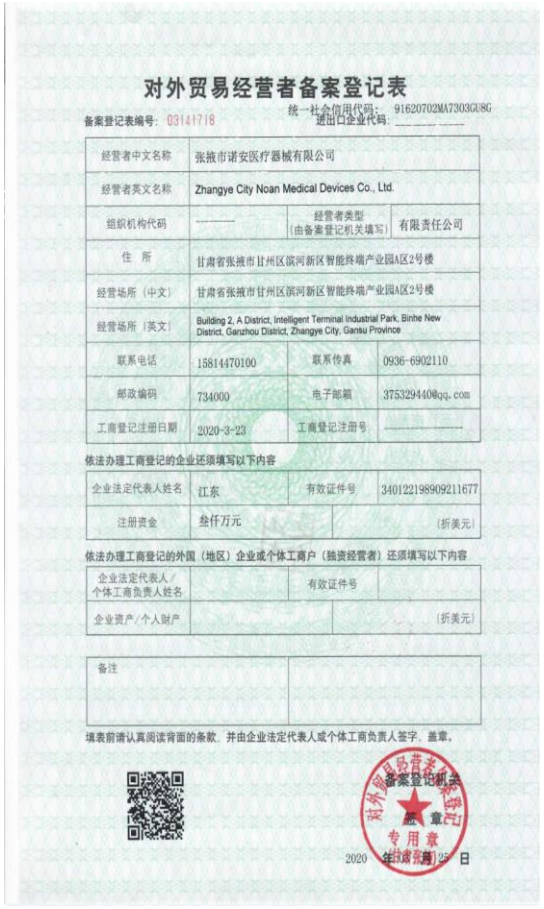
样 品 名 称： 非接触红外额温计

委 托 单 位： 张掖市诺安医疗器械有限公司

检 测 类 别： 委托检测

威凯检测技术有限公司

海关白名单



对外贸易经营者备案登记表

备案登记表编号：03141718　　统一社会信用代码：91620702MA7303GU8G
进出口企业代码：

经营者中文名称	张掖市诺安医疗器械有限公司		
经营者英文名称	Zhangye City Noan 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	甘肃省张掖市甘州区滨河新区智能终端产业园A区2号楼		
经营场所（中文）	甘肃省张掖市甘州区滨河新区智能终端产业园A区2号楼		
经营场所（英文）	Building 2, A District, Intelligent Terminal Industrial Park, Binhe New District, Ganzhou District, Zhangye City, Gansu Province		
联系电话	15814470100	联系传真	0936-6902110
邮政编码	734000	电子邮箱	375329440@qq.com
工商登记注册日期	2020-3-23	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	江东	有效证件号	340122198909211677
注册资金	叁仟万元		（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

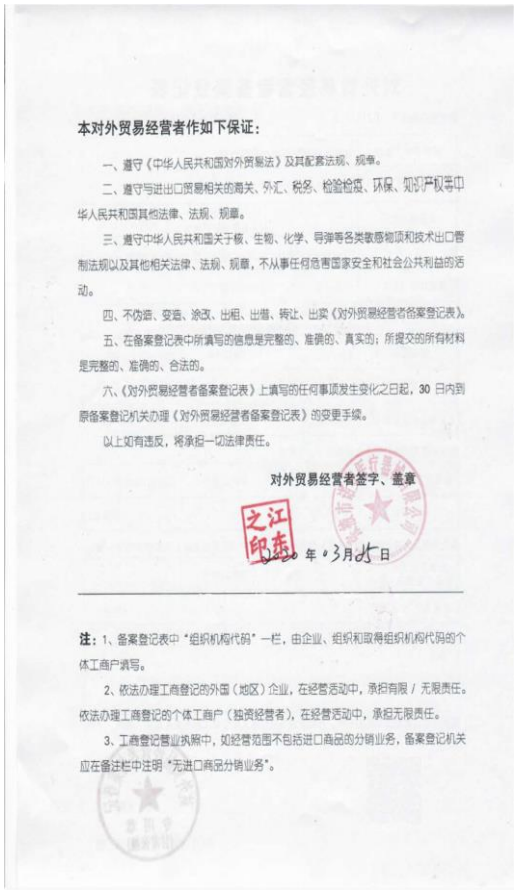
企业法定代表人/个体工商负责人姓名		有效证件号	
企业资产/个人财产			（折美元）

备注	

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。

备案登记机关盖章

2020 年 3 月 25 日



本对外贸易经营者作如下保证：

一、遵守《中华人民共和国对外贸易法》及其配套法规、规章。

二、遵守与进出口贸易相关的海关、外汇、税务、检验检疫、环保、知识产权等中华人民共和国其他法律、法规、规章。

三、遵守中华人民共和国关于核、生物、化学、导弹等各类敏感物项和技术出口管制法规以及其他相关法律、法规、规章，不从事任何危害国家安全和社会公共利益的活动。

四、不伪造、变造、涂改、出租、出借、转让、出卖《对外贸易经营者备案登记表》。

五、在备案登记表中所填写的信息是完整的、准确的、真实的；所提交的所有材料是完整的、准确的、合法的。

六、《对外贸易经营者备案登记表》上填写的任何事项发生变化之日起，30 日内到原备案登记机关办理《对外贸易经营者备案登记表》的变更手续。

以上如有违反，将承担一切法律责任。

对外贸易经营者签字、盖章

江东

2020 年 3 月 25 日

注：1、备案登记表中“组织机构代码”一栏，由企业、组织和取得组织机构代码的个体工商户填写。

2、依法办理工商登记的外国（地区）企业，在经营活动中，承担有限 / 无限责任。依法办理工商登记的个体工商户（独资经营者），在经营活动中，承担无限责任。

3、工商登记营业执照中，如经营范围不包括进口商品的分销业务，备案登记机关应在备注栏中注明“无进口商品分销业务”。



海关进出口货物收发货人备案回执

企业名称	张掖市诺安医疗器械有限公司
统一社会信用代码	91620702MA7303GU8G
海关备案日期	2020-03-27
海关编码	620796029P
检验检疫备案号	6251400011
有效期	长期

中华人民共和国酒泉海关

2020年3月27日

自然人、法人或者非法人组织可通过“中国海关企业进出口信用信息公示平台”（http://credit.customs.gov.cn）或者“互联网+海关”（http://online.customs.gov.cn）查询海关公示的企业信息。

第二类医疗器械经营备案凭证

备案号:甘区食药监械经营备 0493 号

企业名称：张掖市诺安医疗器械有限公司

住　　所：甘州区滨河新区智能终端产业园A区2号楼

经营场所：甘州区滨河新区智能终端产业园A区2号楼

库房地址：甘州区滨河新区智能终端产业园A区2号楼

法定代表人：江　东

企业负责人：江　东

经营范围：二类医疗器械

备案部门(公章)

备案日期2020年03月04日

企业投资项目备案表

备案证号：区发改发（备）〔2020〕5号

项目名称	张掖智能终端产业园医疗用品及器材制造项目	项目代码	2020-620702-27-03-001166
建设地点	甘肃省:张掖市_甘州区	项目总投资额（万元）	3000
建设性质	新建	建设规模及内容	医疗仪器设备及器械制造；医疗设备经营租赁；医疗用品及器材批发；基层医疗卫生服务。（口罩生产线1条，红外线体温枪生产线2条，根据实际经营状态扩建。）
计划建设时限	2020年-2020年		
项目单位名称及号码	张掖市诺安医疗器械有限公司：91620702MA7303GU8G	项目单位证照类型	统一社会信用代码(三证合一)
姓名及电话	江东：15814470100	项目单位注册地址	
本项目单位承诺： 本项目的信息真实、完整、正确，符合国家、甘肃省相关产业政策,如有违法违规情况，愿承担相应的法律责任。		甘肃省甘州区发展和改革局项目备案专用章 2020-02-21	

CE证书及查询方法



Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Form QAT_10-M05, version 00, effective since March 25th, 2020

Certificate of Compliance

No. 0H200404.ZNMDO64

Test report no. PTC200310045S-LD01, PTC200310045E-EM01

Certificate's Holder: Zhangye Nuoan Medical Equipment Co., Ltd.
No.2, Intelligent terminal industrial zone A, Binghe new district, Ganzhou district, Zhangye City, Gansu province.

Certification ECM Mark: Type Approved

Product: Non contact infrared thermometer

Model(s): T-01

Verification to: Standard:
EN 55011:2016+A1:2017, EN 60601-1-2:2017,
EN 61000-3-2:2014, EN 61000-3-3:2013
EN 60601-1:2006+A11:2011+A1:2013+A12:2014

related to CE Directive(s):
2014/35/EU (Low Voltage)
2014/30/EU (Electromagnetic Compatibility)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 04 April 2020

Expiry date: 03 April 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 +39 051 6705156 info@entecerma.it www.entecerma.it

证书查询指引

第一步：打开网址：
http://certificate.entecerma.it/en/CertificateVerification.aspx#

第二步：输入证书号（大小写要保持一致），点Verify.

最终：查询到信息。

机构资质查询

第一步：输入网址：
https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main

第二步：选93/42/EEC（这是MDD指令）

第三步：：将会显示获得该资质授权的NB机构名录,然后找到NB1282

FDA证书及查询方法



Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

ZHANGYE NUOAN MEDICAL EQUIPMENT CO.,LTD

Building 2, zone A, intelligent terminal industrial park, binhe new district, ganzhou district

Zhangye, Gansu, 734000, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.

Owner/Operator Number: 10066609

Listing No.	Product Code:	Device Name:
D384273	PXH	Thermometer kit- Thermometer T-01 T-02 T-03

UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. UCL-REG SERVICE INC. 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. UCL-REG SERVICE INC. 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."

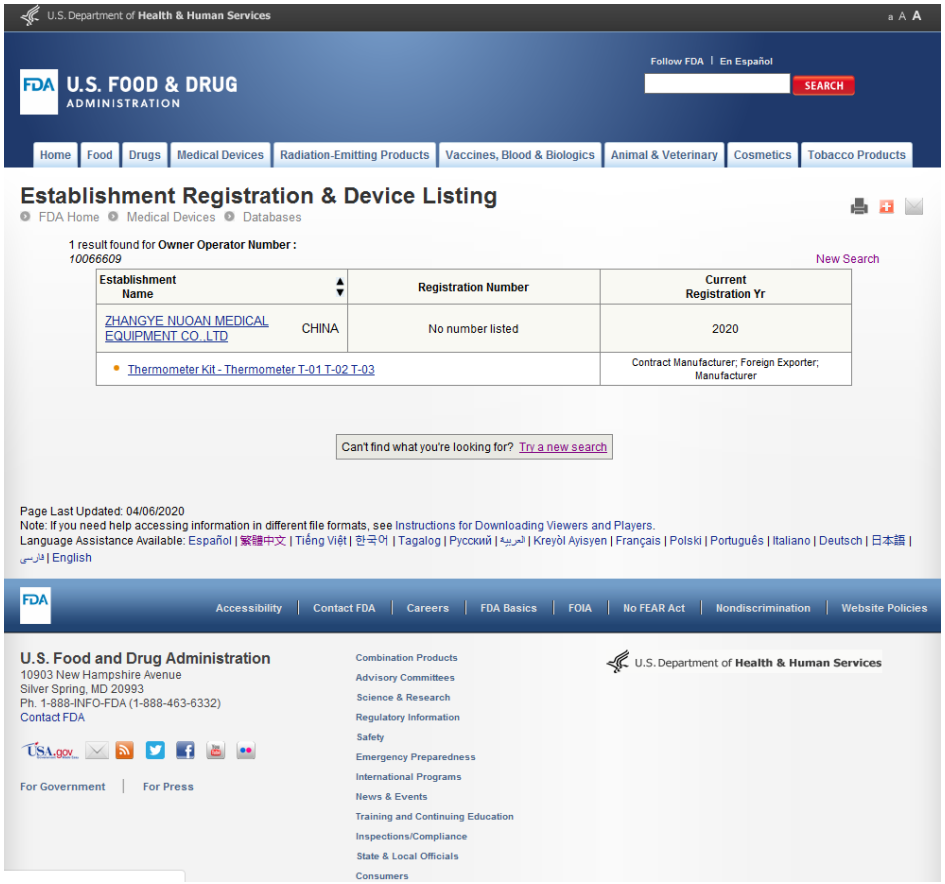
The U.S.Food and Drug Administration does not issue a certificate of registration, nor does the U.S Food and Drug Administration recognize a certificate of registration, UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.

UCL-REGSERVICE INC.
602 ROCKWOOD ROAD.WILMINGTON,
NEW CASTLE DE 19802 USA

UCL-REG SERVICE INC.

Cert. No.: M20810
Issued Date: 2 April 2020
Expiration Date: 31 December 2020

FDA官网认证号查找结果



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

1 result found for **Owner Operator Number :**
10066609

New Search

Establishment Name		Registration Number	Current Registration Yr
ZHANGYE NUOAN MEDICAL EQUIPMENT CO.,LTD	CHINA	No number listed	2020
• Thermometer Kit - Thermometer T-01 T-02 T-03			Contract Manufacturer; Foreign Exporter; Manufacturer

Can't find what you're looking for? Try a new search

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FCC、PSE



精准检测
PRECISE TESTING

SDoC's Compliance Information Statement

No.: PTC20031004501E-FC01

Applicant	:	Zhangye Nuoan Medical Equipment Co.,Ltd
Address	:	No.2, Intelligent terminal industrial zone A, Binghe new district, Ganzhou district, Zhangye City, Gansu province
Manufacturer	:	Zhangye Nuoan Medical Equipment Co.,Ltd
Address	:	No.2, Intelligent terminal industrial zone A, Binghe new district, Ganzhou district, Zhangye City, Gansu province
Trade Mark	:	N/A
Product	:	Non contact infrared thermometer
Model No.	:	T-01

The submitted sample of the above equipment has been tested and found to comply with the following requirement of 47 CFR of PART 15.
The assessment of compliance of the product with the requirements relating to FCC rules was based on the following standards and procedure:

Applicable Standard(s)	Test Report(s) Number
FCC Part 15, Subpart B ANSI C63.4:2014	PTC20031004501E-FC01

This verification is part of the full test report(s) and should be read in conjunction with it. This verification is based on an evaluation of one sample of above mentioned product. It does not imply assessment of the production of the product. Without the written approval of Precise Testing & Certification (Guangdong) Co., Ltd. , this verification is not permitted to be reproduced, except in full. It is not permitted to use the test lab's logo.

FC

PRECISE TESTING & CERTIFICATION (GUANGDONG) CO.,LTD

Jacky Ou
Manager
Date: March 23, 2020

Precise Testing & Certification (Guangdong) Co., Ltd.
Building 1, No.6, Tongxin Road, Dongcheng Street,
Dongguan, Guangdong, China
Tel: 86 769 38808222 Web:www.ptc-testing.com
Mail: inquiry@ptc-testing.com



精准检测
PRECISE TESTING

CERTIFICATE OF CONFORMITY

No.: PTC20031004501S-PE01

Applicant	:	Zhangye Nuoan Medical Equipment Co.,Ltd
Address	:	No.2, Intelligent terminal industrial zone A, Binghe new district, Ganzhou district, Zhangye City, Gansu province
Manufacturer	:	Zhangye Nuoan Medical Equipment Co.,Ltd
Address	:	No.2, Intelligent terminal industrial zone A, Binghe new district, Ganzhou district, Zhangye City, Gansu province
Factory (ies)	:	Zhangye Nuoan Medical Equipment Co.,Ltd
Address	:	No.2, Intelligent terminal industrial zone A, Binghe new district, Ganzhou district, Zhangye City, Gansu province
Trade Mark	:	N/A
Product	:	Non contact infrared thermometer
Rating	:	Battery: 3.0Vdc
Model No.	:	T-01

The submitted sample of the above equipment has been tested and found to comply with the following Japanese Directive.
The standard(s) used for showing compliance with the essential requirements:

Applicable Standard(s)	Test Report(s) Number
J60335-1(H27)	PTC20031004501S-PE01

This certificate is part of the full test report(s) and should be read in conjunction with it. This certificate is based on an evaluation of one sample of above mentioned product. It does no imply assessment of the production of the product. Without the written approval of Dongguar Precise Testing & Certification Corp., Ltd., this certificate is not permitted to be reproduced except in full. It is not permitted to use the test lab's logo. The PSE marking may only be used if all the relevant and effective Japanese Directives are applicable.

PS E

PRECISE TESTING & CERTIFICATION (GUANGDONG) CO.,LTD

Jacky Ou
Manager
Date: March 27, 2020

Precise Testing & Certification (Guangdong) Co., Ltd.
Building 1, No.6, Tongxin Road, Dongcheng Street,
Dongguan, Guangdong, China
Tel: 86 769 38808222 Web:www.ptc-testing.com
Mail: inquiry@ptc-testing.com

医疗物资声明

出口医疗物资声明

Export Declaration of Medical Supplies

兹声明，本次报关出口医疗物资信息如下：

We hereby declare as follows the export information of medical supplies for this customs declaration:

产品名称（含规格、型号）Product Name (including specifications and model)	产品数量 Product Quantity	国外质量标准名称 The Name of Quality Standards of the Foreign Country	国外质量标准要求 Quality Requirements of the Foreign Country	进口国（地区）Importing Country/ Region	生产厂商 Producer
T-01 非接触红外额温计 T-01 Non-contact thermometer	[illegible]个	CE	CE	意大利 (Italy)	张掖市诺安医疗器械有限公司 Zhangye C[illegible] Nuan M[illegible]al Devices co, Ltd

上述产品取得医疗器械产品注册证书，符合意大利地区相关质量标准和安全要求。我公司对以上内容承担如实申报之责任。

The above products are certified or registered by Medical product registration certific[illegible]n and compliant with relevant quality standards and safety requir[illegible]ts of Italy country/region. Ou[illegible]mpany is responsible for the truthful declaration of the above informa[illegible].

特此声明。

张掖市诺安医疗器械有限公司
Zhangye City Nuan Medical [illegible]ices co, Ltd
2020 年 [illegible] 月 28 日
Day/Month/Year

合格证

合格证 (CERTIFICATION)

产品名称 (Product name)	红外线体温计 Infrared thermometer
产品型号 (Product number)	T-01
测量距离 (Measuring range)	3-5CM
企业标准 (Measuring distance)	GB/T 14710-2009
注册证号/产品技术要求编号 (Registration number)	甘械注准20202070030
生产许可证号 (Producting License)	甘食药监械生产许20200003号
生产企业 (Manufacturer)	张掖市诺安医疗器械有限公司 Zhangye City Nuan Medical Devices Co.,Ltd
生产地址 (Production address)	甘肃省张掖市甘州区滨河新区智能终端产业园A区2号楼 Building 2,A District,Ganzhou Terminal Industrial Park,Binhe New District,Ganzhou District,Zhangye City,Gansu Province
生产日期 (Production Date)	25 APR 2020
生产批次 (Production batch)	20200425
有效期 (Term of validity)	一年
检验日期 (Inspection date)	25 APR 2020
检验员 (Inspectors)	PASS Check12

红外体温计展示


KANGYOUMEI
NON - CONTACT INFRA-
RED THERMOMETER
EASY TO USE
UNIT SWITCHING
T-01













实物包装


KANGYOUMEI
NON - CONTACT INFRA-
RED THERMOMETER
EASY TO USE
UNIT SWITCHING
T-01


Product parameters
Voltage supply: direct current (2 triple A batteries)
Measuring range: 32°C ~ 43°C
Accuracy of measurement: ±0.2°C
Measuring distance: 3 ~ 5cm
Measuring time: 1 second
Automatic shutdown: after 1 min
Dual color backlight: Green for 34.0°C ~ 37.3°C
Red for 37.4°C ~ 42.0°C
Transport & Storage temperature: -20°C ~ 55°C
Relative humidity: <93%
Working environment ambient temperature: 16.0°C ~ 35°C
Relative humidity: <85%
Service life: 1 year
Manufacturer: Zhangye nuo'an medical equipment co. LTD
Production address: Building 2, zone a, intelligent terminal Indus-
trial Park, Binhe New District,Ganzhou District,Zhangye City,
Gansu Province
Production license: Gyjs production license No: 20200007(Provi-
sional)
Product registration certification: 20162200513
Technical requirement: 20162200513
Please refer to the instruction for other information
Please read the instructions carefully


KANGYOUMEI
PRESS 1 BUTTON TO MEASURE
20
20 SETS OF MEMORY DATA
Easy to use
Acousto-optic warning
Infrared


KANGYOUMEI
20
How to use:
Press the power button to turn on----keep the distance about 5-10cm from the target---press the measurement button-----measure-ment completed when you hear a prompt tone

实物细节


KANGYOUMEI
NON - CONTACT INFRA-
RED THERMOMETER
EASY TO USE
UNIT SWITCHING
T-01


KANGYOUMEI
Product parameters




Set up
Non - contact infrared thermometer





单箱及出口包装





产品规格

Description & Packageing	Model	Factory	Unit	Material	Quantity	Size	E. W.
描述	型号	生产厂家	单位	材质	数量	单品尺寸	单只净重
Non-Contact Infrared Thermometer	T-01	NuoAn	1	ABS+PC	1	150*95*44mm	116g(without batt.)

箱规

Carton	G.W.	N.W.	CBM	Spec.
外箱包装尺寸	每箱毛重	每箱净重	每箱体积	包装
615*352*250mm	8.3KG	5.8KG	0.0541	1pc/bag 50pc/ctn

说明书

Operating instruction

Non - contact infrared thermometer T-01

1. Available range

Temperature display or data output is measured by infrared temperature sensing method

Structure composition: shell, infrared temperature sensor, signal receiving processor, button, buzzer, LCD display, battery, etc

Contraindications: none

2. operating principle

Any object will emit infrared radiation energy, its surface temperature is directly determined.The radiation energy size and wavelength, based on this principle, this product adopts special high precision for detecting infrared radiation energy emitted by the human body with a wavelength of 9~15 μ m

infrared sensor, and through accurate calculation and a variety of compensation, measure your body temperature accurately .

3.Product characteristics

Infrared contact measurement

Frontal temperature model and physical temperature model:

Fever alarm

LED high brightness dual color backlight (Green is normal and red is high) , clear and soft display

Two temperature units of Celsius and Fahrenheit are optional:

Automatic shutdown, energy saving;

32 sets of measured values are stored in memory for easy reference.

4.Technical parameters

Measurement method: contact type

Measuring range: Body temperature32℃-42.9℃(89.6° F-109.2° F

Accuracy: Body temperature ↓ above (35-42) ℃, ±0.3℃/0.54° F

Display resolution: 0.1℃/° F

Requirements of environment: 16-35℃ (60.8-95° F) RH≤85% (non-condensing)

Storage environment requirements: -20℃-55℃ (-4° F-131° F) Rh≤ 95% (non-condensing)

Shutdown time: Automatic shutdown without any operation within 55 seconds

Voltage: DC 3V (2AAA 7#)

Consumed power: Off state<6uW

When the machine is turned on and measured <45mW

net weight: 99g, With package (including battery): 178g;

Gross weight of case: 7.25KG

5. Product Structure Diagram

1. LED display screen
2. Measurement
3. Sensor
4. Battery cover
5. Function setting key
6. Memory group increased
7. Memory group increased



6. Icons define

Icon definition	icon	State description
data display	888	Measurement value display
Temperature unit	surface temperature	surface temperature
	℃	Centigrade
	°F	Fahrenheit degree
Memory symbols	Memory	The display value is the latest 32 sets of memory values
		The product is type B equipment of type 2
		Production batch number
		The manufacturing date
electromagnetic compatibility		1 group of class B equipment
List of accessories		One battery pair, one operation manual and one qualification certificate
		warning
		Please do not throw away after use
		General precautions
		Please refer to the instruction before using
		Low voltage

7. Safety instructions

1. The surface temperature

Open the battery cover and install the battery, boot into the measurement mode. Put the thermometer before your forehead then press the measurement button ,when you hear "di" ,a measurement completed, the screen shows the measured value.

2. Object mode

Open the battery cover and install the battery. Turn on it and enter the measurement mode. Point it at the object and press the measurement button.When you hear "di",a measurement is completed.

8. Setting

1. Memory value

Open the battery cover and install the battery. Press the setting key again to display the last measured value on the screen. Press the "+/-" button again view the last 32 sets of measurements

2. Voice switch

In the power-on state, long press the setting button for 3 seconds to "di". When the speaker icon is displayed press the "+/-" button to switch to " F and " C .Press the Settings key to confirm.

3. Temperature unit setting

In the power-on state, long press the setting button for 3 seconds, and press the "+/-" button to switch when the icon is displayed.Press the Settings key to confirm.

a. The display temperature exceeds the range of 32.0℃~42.9℃, indicating error Lo or HI

b. The ambient operating temperature exceeds the range of 16℃~35 ℃, indicating error Lo or HI

4.Low voltage prompt function

When the battery voltage is lower than 2.4±0. 0.2v, it will display the low voltage symbol and shut down automatically.

5.Fever warning

When a fever is measured, the screen turns to red.

9. Cautions and warnings

1.points for attention

please read the product manual carefully before using and confirm that the battery has been installed.

Do not put the thermometer into any liquid, do not put it in the high or low temperature environment for a long time;

No collision, falling and mixing of sharp objects,do not disassemble by yourself

Do not use in the strong electromagnetic interference environment;

Please place the product out of the reach of children;

It is recommended to practice many times to be familiar with the measurement method and try not to change the factory settings of the product;

Measurement results can not replace physician diagnosis;

There is no need for special maintenance during use. Please contact the seller or manufacturer if there is any trouble.

2. warning

1.Please keep the battery away from children, otherwise children may eat by mistake. If swallowed,please contact the doctor immediately.

2.High fever or long-term fever need medical treatment. Especially for children, Don' t judged and treated by yourselves- Please consult the doctor in time.

Tips:

1. Please use the thermometer in a stable temperature environment. When the ambient temperature changes greatly(such as from indoor to outdoor), please leave it for about 30 minutes before measurement;

2. Do not measure the temperature of an extremely high or low temperature object immediately after the temperature, please leave it for 10 minutes before the measurement.

3. When the measured object comes from a place with a large difference from the measured ambient temperature, it shall stay in the test environment for at least 30 minutes;

4. Try not to measure under the circumstance such as forehead hair dryer, drench water, perspire, beamear, put on makeup, do not measure temperature within 30 minutes after exercise, bath, have a meal.

10. Battery replacement

Open the battery cover and remove the old battery;

Put in two new AAA (no. 7) batteries, please note the positive and negative direction;

After the battery is installed, the screen is fully displayed. When you hear a "di" sound, it can be use again. ,

If there is no prompt sound, please check the positive and negative direction of the battery.

warning

1.When not used for a long time, please take out the battery, beware of leakage, do not put the battery in the fire;

2.Dispose of waste batteries according to local regulations to avoid pollution;

3.This product can only replace batteries, If other parts or materials are used, safety will be reduced.

11. Maintenance and cleaning

Since the thermometer is used repeatedly, please pay attention to cleaning and maintenance before using it.When not used for a long time, please keep the inner cavity of the thermometer probe clean to avoid the dirt of thermometer probe and inaccurate measurement results.

Cleaning:

1.Surface cleaning: Wipe the sensor probe gently with a clean soft cloth or cotton stick with a little medical alcohol. .

12. Troubleshooting

description	cause	Processing method
(H)	Temperature measurement mode: the measured temperature value is higher than 42. 9 ℃ Physical temperature measurement mode: the measured temperature value is higher than 100 ℃	Please use it within the measurable temperature range. If there is another error display, please contact the customer service center.
(Lo)	Temperature measurement mode: the measured temperature value is higher than 32.0 ℃ Physical temperature measurement mode: the measured temperature value is higher than 0	
(Err)	16.0℃~35.0℃ (60.8° F~95.0° F) Ambient temperature out of normal operating temperature range	Please leave the product in normal working environment for at least 30 minutes before using it.

13. EMC Information

Guide and manufacturer's statement - electromagnetic launc

The product is intended to be used in the following electromagnetic environment, and the buyer or user of the product should guarantee
It is used in this electromagnetic environment:

Launch the experiment	Conformance	Electromagnetic environment - guide
RF emission GB4824	1 group	This product only uses RF energy for its internal functions. As a result, its RF emission is very low and may not cause any interference to nearbyelectronic equipment.
RF emission GB4824	Class B	This product is not applicable to all equipment used in the household and directly connected to the residential public low-voltage power supply network.
Harmonic emission	not applicable	
Voltage Fluctuation/scintillation emission	not applicable	

Guide and manufacturer's statement - electromagnetic immunity

The product language is intended to be used in the following electromagnetic environment, and the buyer or user of the product should ensure that it is used in such electromagnetic environ

Immunity test	IEC60601	Electric potential	Electromagnetic
GB/T 17626.2 electrostatic discharge	±6kV Contact discharge ±8k Air discharge	±6kV Contact discharge ±8k Contact discharg	The floor should be made of wood, concrete or tile. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
GB/T 17626.4 Electrical fast transient pulse group	0.5kV for Power line ±1kV for input / output lines	Not applicable	The network power supply should be of the quality that is typically used in a commercial or hospital environment.
surge GB/T 17626.5	±1kV Line to line ±2kV Line to ground	Not applicable	The network power supply should be of the quality that is typically used in a commercial or hospital environment.
Voltage sag, short interruption and voltage change on power input line GB/T 17626.11	< 5% UT for 0.5 weeks (on UT, > 95% Temporary descent) 40% UT for 5 weeks (on UT, 60% Temporary descent) Plot for 25 weeks (on UT, 30% Temporary descent) < 5% UT for 5S (on UT, 95% Temporary descent)	Not applicable	The network power supply should be of the quality that is typically used in a commercial or hospital environment. If the user of the product needs continued operation during power supply failure, it is recommended to use uninterruptible power supply or battery power supply.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m/50Hz	The power frequency magnetic field should be at the level of the characteristic place of the typical location in the typical commercial or hospital environment

Note: UT refers to the ac network voltage before the test voltage is applied

Recommended isolation distance between portable and mobile rf communication equipment and the product

The product is intended to be used in an electromagnetic environment where radio frequency harassment is controlled.According to the maximum output power of communication equipment, the buyer or user of this product can prevent electromagnetic interference by maintaining the minimum distance between

Maximum rated output of transmitter	The isolation distance corresponding to different frequencies of the		
	150kHz~80MHz d=1.2√p	80MHz~800MHz d=1.2√p	800MHz~2.5GHz d=2.3√p
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the rated maximum output power of the transmitter not listed in the table above, the isolation distance d is recommended, in meters (M), which can be determined by the formula in the frequency bar of the corresponding transmitter. Here, p is the maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W) .

Note 1: at 80MHz and 800MHz, the formula of higher frequency range should be used.

Electromagnetic compatibility

Attention:

- This product confoms to relevant requirements of YY0505 electromagnetic compatibility.
- The user shall install and use the emc information provided in the random file.
- Portable and mobile RF communication equipment may affect the performance of the product, and avoid strong electromagnetic interference when using, such as near to mobile phones, microwave ovens, etc.

Please refer to the attachment for details of the guide and manufacturer's statement.

Warning:

The equipment or system shall not be close to or stacked with other equipment. If it must be used close to or stacked, observe and verify that it can operate normally in the configuration in which it is used.

Guide and manufacturer's statement - electromagnetic immunity

The product is used in the following electromagnetic environment, and the buyer or user shall ensure that it is used in such electromagnetic environment:

Immunity test	Test electricity	Electric potential	Electromagnetic Environment-Guidelines
	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile rf communication equipment shall not be used closer to any part of the product than the recommended isolation distance, including the cable, which shall be calculated by a formula corresponding to the transmitter frequency. Recommended isolation distance d=1.2√p
	3V/m 80 MHz to 2GHz	3V/m	According to the maximum output power rating of transmitter provided by transmitter manufacturer, unit: Watt (W) . following symbols.

The field strength of a stationary rf transmitter, as determined by surveying the electromagnetic field a, and it shall be less than the compliance level in each frequency range b. Interference may occur near equipment marked with the following symbols:

Note 1: at 80MHz and 800MHz, the formula of higher frequency band is used.

Fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and ground mobile radios, amateur radios, us and FM radio broadcasts, and television broadcasts, are theoretically unpredictable in field strength. To assess the electromagnetic environment of fixed rf transmitters, a survey of electromagnetic field should be considered. If the field strength of the place where the product is located is higher than the RF compliance level used above, the product shall be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or positioning the bs7881 oxygen enriched soft oxygen chamber.

In the whole frequency range of 150kHz-80mHz, the field strength should be lower than [V] / m.

14. After-sales service

This product provides one year(warranty.

repair service will not be provided for any damage caused by user's personal fault or unauthorized demolition.

Tips:

Please keep the purchase voucher for future maintenance.Beyond the service life of the product can not be used, otherwise it may cause measurement errors and inaccuracies.

15.Company information

Registrant/Manufacturer /Customer service:Zhongze mua ;an medical equipment co. LTD

Residence/Production address:Building 2, zone A, intelligent terminal industrial park, Binhe new district, Ganzhou district, Zhangzo , Gansu.

Product technical requirements No. Guangdong ynuoan enfuda(2019)0218

Medical device production license No.: Production license(xk)

production license No. 20200007

Medical device registration certificate no. : Gan machinery (nonin-standard 20201140014 (temporary)

date of manufacture: See label

Service life: 3 years

TEL: 0596-6902110

Version: 1.2

Revision date: 2020.02

Warranty/warranty card

Product quality assurance certificate:

1. From the date of purchase, within 3 months, the company will provide free warranty service for 3~12 months. users need to bear the relevant postage.

2. Our company will not provide free warranty service for the following faults caused by users' personal reasons.

The details are as follows:

(1) Failure caused by unauthorized disassembly or modification

(2) Internal malfunction caused by accidental fading in the process of taking or using;

(3) Failure caused by improper use or lack of proper maintenance.

(4) Did not operate according to the correct knowledge on the operating instructions

(5) caused by natural disasters, such as flooding and fire;

(6) improper repair by a repair shop not authorized by our company.

You must present a valid warranty card and proof of purchase when requesting free service.

4. When you need warranty service, please bring this product to the place of sale for maintenance.

5. Repair service beyond the warranty will be charged according to the regulations.

6. The calibration period of this equipment is 2 years, the calibration unit: the manufacturer, the service life: 5 years.

7. When the machine and battery are scrapped, please comply with local regulations.

This product has passed CE and RoHS certification.

warranty card

Product model: _____

product ID: _____

Supplier: _____

Purchase date: ____Year____Month____day

Unit Seal: _____

____Year____Month____day