

Non-Contact Infrared Thermometer

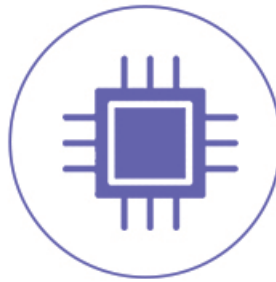
MODEL:IR 988



FEATURES



In 1 Sencond



Smart Chip



High temperature alarm



32 Units Memory array



Non-contact infrared



Large screen display

Suitable for all people



Community



Family



Enterprises and
Institutions

Medical grade for accurate temperature measurement



Display range: 34.8°C~42.5°C

TEMP resolution: 0.1°C/°F

Max. allowable error: $\pm 0.2^{\circ}\text{C}$

1  **ONE**
S **SECOND**



Non-Contact Infrared Thermometer

No contact, no panic, safe,
easy and hygienic





HIGH TEMPERATURE ALARM

AUTOMATIC ALARM SYSTEM

WHEN HIGH BODY TEMPERATURE OCCURS



IN THE HUMAN BODY MODE, THE PRODUCT CAN INTELLIGENTLY DISPLAY THE TEMPERATURE RESULTS AND PROMPT WITH DIFFERENT COLORS, AS FOLLOWS:

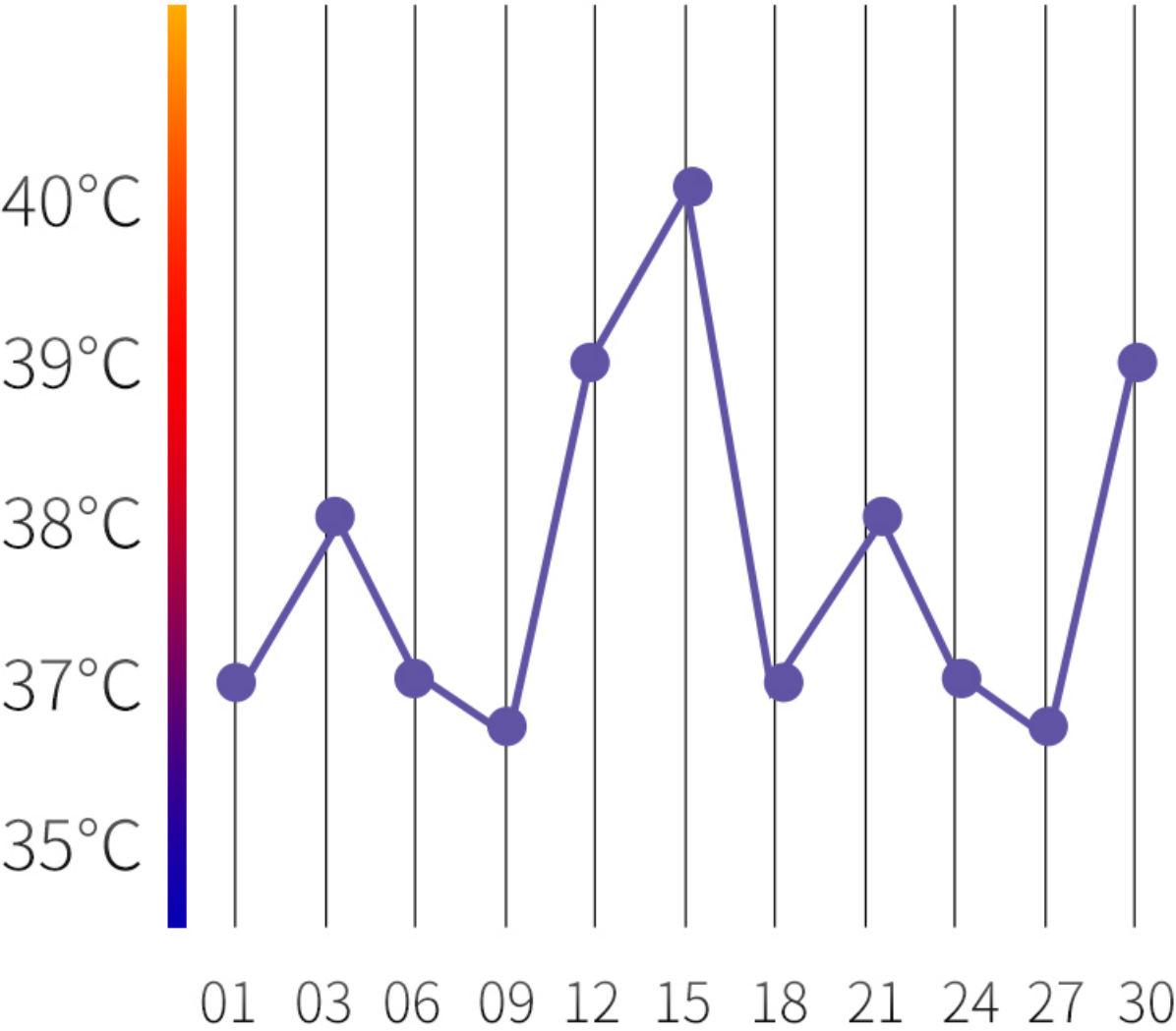
32.0°C -37.4°C GREEN

37.5°C -37.9°C ORANGE

38.0°C -42.9°C RED

32 Units Memory Array

Easy to compare body temperature changes



Auto Standby



Three test modes

Adult / Child / Object



Normal body temperature range:

Underarm: 34.7 ~ 37.3 ° C / 94.5 ~ 99.1 ° F
Oral: 35.5 ~ 37.5 ° C / 95.9 ~ 99.57 ° F
Rectum: 36.6 ~ 38.0 ° C / 97.9 ~ 100.41 ° F

By age:

0-2 years old	36.4-38.0 ° C
3-10 years old	36.1-37.8 ° C
11-65 years old	35.9-37.5 ° C
65 years and over	35.8-37.4 ° C

Object:

0 ~ 93 ° C





single box:16*10.2*5cm

net weight:123G/ box

sealing:80/ box

box:52*39*34CM

Gross Weight:13.5KG/ box



统一社会信用代码
91441300MA520ULA5G

营业执照

(副本) (副本号:1-1)



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 惠州市小欧科技有限公司
类型 有限责任公司(自然人独资)
法定代表人 汪华
经营范围 研发、生产、销售:第一类医疗器械、非接触式
红外线测温仪、非接触式红外线测温设备、电子
产品、智能家居、家居用品、数码产品、家用电
器、户外用品、LED照明灯、香薰机、加湿器、空
气净化器、风扇、智能水杯、体脂称、电子烟、
饰品、美容产品、车载用品、无人飞机、智力玩
具、移动电话、电子计算机及外围设备、软件及
辅助设备;国内贸易,网上贸易代理,货物或技
术进出口;展览展示策划。(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。)〓

注册资本 人民币壹佰万元
成立日期 2018年07月17日
营业期限 长期
住所 惠州市仲恺高新区西坑工业区113
号(厂房D)三楼

登记机关

2020



2020年8月28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

开户许可证

核准号: J5950025008801

编号: 5810-06426788

经审核, 惠州市小欧科技有限公司

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) 汪华

开户银行 中国建设银行股份有限公司惠州陈江金湖支行

账号 44050171004600000722

发证机关(盖章)
2018年08月09日



中华人民共和国医疗器械注册证

注册证编号：粤械注准 20202070349

注册人名称	惠州市小欧科技有限公司
注册人住所	惠州市仲恺高新区西坑工业区 113 号（厂房 D）三楼
生产地址	惠州市仲恺高新区西坑工业区 113 号（厂房 D）三楼
产品名称	红外体温计（疫情应急产品）
型号、规格	IR988
结构及组成	由外壳、红外温度传感器、信号接收处理器、按键、COB 板、蜂鸣器及液晶显示屏组成。
适用范围	通过测量人体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	无
备注	本产品按照《广东省防控新型冠状病毒感染的肺炎疫情期间药品医疗器械行政许可应急审批程序》批准，注册证有效期 1 年，自 2020 年 04 月 08 日起至 2021 年 04 月 07 日止。有效期届满 6 个月前提出延续注册应当在医疗器械注册证有效期届满 6 个月前提出。

审批部门：广东省药品监督管理局

批准日期：2020 年 04 月 08 日

有效期至：2021 年 04 月 07 日

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: 粤食药监械出 20200449 号

Certificate NO.: 粤食药监械出 20200449 号

产品名称: 红外体温计 (疫情应急产品)

Product (s): Non-contact infrared thermometer

规格型号: IR988

Model: IR988

产品注册或备案凭证号: 粤械注准 20202070349

Registration certificate (s): 粤械注准 20202070349

生产企业: 惠州市小欧科技有限公司

Manufacturer: Huizhou Xiaou Technology Co., Ltd

生产企业住所: 惠州市仲恺高新区西坑工业区 113 号 (厂房 D) 三楼

Address of manufacturer: 3rd Floor, No.113(Plant D).Xikeng Industrial Zone, Zhongkai High-tech Zone, Huizhou, Guangdong, China

生产许可或备案凭证号: 粤食药监械生产许 20203582 号

Manufacturing License (s): 粤食药监械生产许 20203582 号

兹证明上述产品已准许在中国生产和销售。

This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效有效期至: 2021 年 04 月 07 日

This certification valid until: 07/04/2021

备注: /

Remark: /



医疗器械生产许可证

许可证编号:粤食药监械生产许20203582号

企业名称:惠州市小欣科技有限公司

生产地址:惠州市仲恺高新区西坑工业区113号(厂房D)三楼

法定代表人:汪华

生产范围:见医疗器械生产产品登记表

企业负责人:贾雪飞

住所:惠州市仲恺高新区西坑工业区113号(厂房D)三楼

发证部门:广东省药品监督管理局

有效期限:至 2025 年 04 月 09 日 发证日期: 2020 年 04 月 10 日

国家食品药品监督管理总局制

CERTIFICATE OF ACCREDITATION



Medical device quality management system

Registration No. 63514Q80350ROS

We hereby certify that

Huizhou Xiaou Technology Co., Ltd.

3rd Floor, No. 113(Plant D), Xikeng Industrial Zone, Zhongkai High-tech Zone, Huizhou, Guangdong, China

The established medical device quality management system conforms to

ISO 13485:2016

Scope of certification/registration

Medical Devices, non-contact infrared temperature detector, electronic products, health measurement device research and development, production and sales

Issue date of this certificate: Mar 17, 2020 Valid date of this certificate: Mar 16, 2021

First registration: Mar 17, 2020 Registration deadline: Mar 16, 2023

(The effectiveness of this certificate shall be validated by periodic surveillance audit of ISP for maintenance.

The intervals of not more than 12 months. Conditions on effectiveness of certificate see <http://www.isp-acpc.com>

Note: the use of outside mainland China)



Issued by:



INSPEC INTERNATIONAL
www.isp-acpc.com



Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

HUIZHOU XIAOOU TECHNOLOGY CO.,LTD.

3rd Floor,No.113,Xikeng Industrial Zone,Zhongkai High-tech Zone (Plant D)

Huizhou, Guangdong, 516000, CHINA

Was registered with US Food and Drug Administration, Center for Devices and Radiological Health, pursuant to the Code of Federal Regulations 21 CFR 807, by Shenzhen Huacetong Testing and Certification Co., Ltd

Owner/Operator Number: 10065474

Device Listing#: See annex

Expiration Date: December. 31, 2020

Shenzhen Huacetong Testing and Certification Co., Ltd. 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. Shenzhen Huacetong Testing and Certification Co., Ltd 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. Shenzhen Huacetong Testing and Certification Co., Ltd 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, Shenzhen Huacetong Testing and Certification Co., Ltd is not affiliated with the U.S. Food and Drug Administration.

Executive Director

Issued: Mar.30, 2020

Expiration Date: Dec.31, 2020





Fiscal Year 2020

CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10065474

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
<i>Thermometer kit</i>	<i>PXH</i>	<i>I</i>	<i>D381438</i>	<i>Manufacturer</i>

A handwritten signature in black ink, appearing to read "Tony B.", written over a horizontal line.

Executive Director

Issued: Mar.30, 2020

Expiration Date: Dec.31, 2020



END OF THE ANNEX



Certificate

ICR Polska/CE/V/M4400135

**Name and address of
certificate owner:**

Huizhou Xiaou Technology Co., Ltd.
Floor 3, Building D, No.113, Xikeng Industrial Zone, Zhong Kai High-tech
Zone, Huizhou City

**Name and address of
manufacturer:**

Huizhou Xiaou Technology Co., Ltd.
Floor 3, Building D, No.113, Xikeng Industrial Zone, Zhong Kai High-tech
Zone, Huizhou City

Product name:

Non-contact infrared thermometer

Product types:

IR988

Product trademark:

n/a

- This certificate confirms that the product meets the requirements of the following standard
- The conformity was demonstrated based on following standard(s) listed by European Commission as harmonized with **Directive 93/42/EEC**.

EC Declaration of Conformity
(Annex VII of Directive
93/42/EEC)

Class I according Rule 1 of
Annex IX of Directive
93/42/EEC

EN 60601-1: 2006
EN 60601-1-2: 2015

The certification has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test report(s) No.:

SC(20)-50165A-10-2-MDD

Test conducted by:

CHINA CERREI (SICHUAN) LABORATORY

Certificate issue date:

02.04.2020

Expiration date:

01.04.2025

NOTE:

- This certificate refers to the above mentioned product and its conformity in regards of above mentioned standard(s) was proven on test sample
- This certificate does not imply meeting all essential requirements, assessment of the series-production or any other restricted Notified Bodies conformity assessment procedure appropriate for the product
- This certificate holder shall use this certificate in connection to declaration of conformity and technical data relevant for the product the certificate was issued

Certificate modifications: n/a



ICR Polska Co. Ltd.
Plac Przymierza 6
03-944 Warsaw
www.icrpolska.com
e-mail: icrpolska@icrqa.com

Director: Rafał Kalinowski

Warsaw, 02.04.2020





CERTIFICATE OF EMC COMPLIANCE

According to Directive: 2014/30/EU

Ref. No.: 20ITC0302327

Applicant: Huizhou Xiaoou Technology Co., Ltd.
Address: Floor 3, Building D, No.113, Xikeng Industrial Zone, Zhong Kai High-tech Zone, Huizhou City

Manufacturer: Huizhou Xiaoou Technology Co., Ltd.
Address: Floor 3, Building D, No.113, Xikeng Industrial Zone, Zhong Kai High-tech Zone, Huizhou City

Product : Non-contact infrared thermometer

Brand Name: N/A

Model No.: IR988

The test sample of product has been passed, the test according to requirements of the following standards:

Standard(s):
EN 60601-1-2:2007
EN 61000-3-2 :2006+A1:2009+A2:2009
EN 61000-3-3 :2013

Test report(s) No.:
20ITC0302327E

Based on the voluntary assessment of the product sample and technical file, we confirm that the above-mentioned product meets the requirements of the EC directive.

The CE mark as show below can be used, under the responsibility of the manufacturer or the importer, after completion of an EC declaration of conformity and compliance with all relevant EC directives.



Approved by/Date: _____



Mar. 11, 2020

Shenzhen ITC Product Testing Co., Ltd.

2nd Floor, Building A7, Xinxing Third Industrial Area, Fuhai Road, Fuyong Street Bao'an District, Shenzhen, China
Tel: (86)-0755-33138690 Fax: (86)-0755-23071003 <http://www.itclab.cn/>

FCC TEST REPORT

Client Information:

Applicant: Huizhou Xiaou Technology Co., Ltd.
Applicant add.: Floor 3, Building D, No.113, Xikeng Industrial Zone, Zhong Kai High-tech Zone, Huizhou City
Brand Name: N/A

Product Information:

Product Name: Non-contact infrared thermometer
Model No.: IR988
Derivative model No.: N/A

Test Date: Mar. 06, 2020 to Mar. 13, 2020 Issue Date: Mar. 13, 2020

Test Standard: FCC Part 15, Subpart B: 2016
ANSI C63.4:2014

Test Result: PASS

Tested by	Amanda Chen		Amanda Chen
Reviewed by	Apple Huang		Apple Huang
Approved by	John Liu		John Liu

This test report may be reproduced in full only
Test result presented in this test report is applicable to the tested sample only



CERTIFICATE OF COMPLIANCE

2015/863/EU Restriction of Hazardous Substance

Ref. No.: 20ITC0302329

Applicant: Huizhou Xiaoou Technology Co., Ltd.
 Address: Floor 3, Building D, No.113, Xikeng Industrial Zone, Zhong Kai High-tech Zone, Huizhou City
 Manufacturer: Huizhou Xiaoou Technology Co., Ltd. 未标题-1
 Address: Floor 3, Building D, No.113, Xikeng Industrial Zone, Zhong Kai High-tech Zone, Huizhou City
 Product: Non-contact infrared thermometer
 Brand Name: N/A
 Model No.: IR988

The test sample of product has been passed, the test according to requirements of the following standards:

Standard(s):	Test report(s) No.:
IEC62321-3-1:2013;	20ITC0302329R
IEC62321-4:2013+A1:2017;	
IEC 62321-5:2013; IEC 62321-6:2015;	
IEC 62321-7-1:2015; IEC 62321-7-2:2017;	
IEC 62321-8:2017	

The Certificate of compliance is based 未标题-1 procedure or an evaluation of the above-mentioned product. This is to certify that the above-mentioned product is in compliance with the EU RoHS Directive 2011/65/EU and its amendment directives 2015/863/EU (RoHS 2.0) of the European parliament.

ROHS

Approved by/Date:  Mar. 13, 2020
 Department Manager



Shenzhen ITC Product Testing Co., Ltd.

2nd Floor, Building A7, Xinxing Third Industrial Area, Fuhai Road, Fuyong Street Bao'an District, Shenzhen, China
 Tel: (86)-0755-33138690 Fax: (86)-0755-23071003 <http://www.itclab.cn/>