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Infrared Thermometer



Instructions

The first step



Aim the thermometer probe at the center of the forehead and keep the distance within 5cm (preferably the thickness of the adult index finger). Do not touch the forehead directly.

The second step



Press key "M" to measure

The third step



After the beep prompt, the screen displays the Measured Value.

Product performance

Product name	Infrared thermometer
Product model	H2K-801
Measurement Range	Temperature mode: 34.0°C~42.9°C
Measurement time	≤2 second
Measurement distance	3cm - 5cm
Auto OFF	≤60 second
	34.0°C~34.9°C: ±0.3°C
Measuring precision	35.0°C~42.0°C: ±0.2°C
	42.1°C~42.9°C: ±0.3°C
Memory data	10
Storage environment	-20°C~+55°C, relative humidity: <93%, atmospheric pressure: 70kpa~106kpa
work environment	16°C~35°C, relative humidity: <85%, atmospheric pressure: 70kpa~106kpa
Power supply	DC3V (two AAA alkaline batteries)
Validity period	5 years
accessories	Manual X1, Qualification certification X1

*Please refer to the manual for other contents

Manufacturer: JIANGXI BIGHEALTHY TECH CO., LTD
Address: 1F, Hengtai Technology Park, No.2 Industrial Area, LONGNAN Economic and Development Area, LONGNAN Town, Ganzhou City, JIANGXI Province, China, 341700
Medical Device Registration certification No: Gan Xie Zhu Zhun 20202070253
Production license:

生产企业: 江西宏之康科技有限公司
生产地址: 江西省赣州市龙南县长源经济技术开发区龙南镇第二工业小区 宏康科技园1楼
医疗器械注册证编号: 赣械注准20202070253
生产许可证编号:

Made In China



INFRARED THERMOMETER



Infrared reception

Auto OFF

Large Screen

Multifunction

Press any key to continue

Rapid measurement

backlight display

10 sets of automatic memory

机身尺寸/ body size	101 * 40 * 143 mm
机身重量/ body weight	120g
彩盒尺寸/ color box size	17.4 * 10.9 * 6.3 cm
包装重量/ packaging weight	170g
卡通箱尺寸/ carton size	59 * 36.3 * 29cm
卡通箱重量/ carton weight	8.7kg
一卡通箱/ A carton box	Holding 50 pcs
Container	50,000pcs/40 尺高柜
	38,000pcs/40 尺平柜
	18,000pcs/20 尺高柜

中华人民共和国医疗器械注册证

注册证编号：赣械注准 20202070253

注册人名称	江西宏之康科技有限公司
注册人住所	江西省赣州市龙南县龙南经济技术开发区龙南镇第二工业小区
生产地址	江西省赣州市龙南县龙南经济技术开发区龙南镇第二工业小区
代理人名称	/
代理人住所	/
产品名称	医用红外体温计
型号、规格	HZK-801
结构及组成	由产品外壳、红外传感器、显示屏、数据处理电路板和电池组成。
适用范围	通过红外测量的热辐射值来显示被测对象的体温，用于测量额头部位体温。
附件	产品技术要求。
其他内容	/
备注	应急审批。该产品不得在有电磁干扰的环境下使用，企业还应告知剩余风险。企业应在产品延续注册前按照《医疗器械注册管理办法》的相关规定，继续完成适用标准测试，补齐相关申请材料。

审批部门：江西省药品监督管理局

批准日期：2020年4月26日
有效期至：2021年12月25日



江西省药品监督管理局

网站首页

政务公开

网上办事

公众参与

智慧监管

您当前所在的位置: 首页 > 数据查询 > 医疗器械 > 医疗器械生产许可证



数据查询



食品



药品



医疗器械



化妆品



其他

- 医疗器械生产许可证
- 一类医疗器械生产备案
- 医疗器械经营许可证
- 二类医疗器械经营备案
- 医疗器械注册信息
- 网络交易服务第三方平台备案

许可证编号

企业名称

江西宏之康科技有限公司

注册地址

法定代表人

搜索本栏目

重置

企业名称	许可证编号	生产地址	发证日期	有效期至	发证机关	公示日期	状态
江西宏之康科技有限公司	赣食药监械生产许20200373号	江西省赣州市龙南县龙南镇	2020-04-29	2025-04-28	江西省药品监督管理局	2020-04-29	有效

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显示1到1,共1记录

海关进出口货物收发货人备案回执

企业名称	江西宏之康科技有限公司
统一社会信用代码	91360727MA3958PGX3
海关备案日期	2020-04-29
海关编码	36079665DN
检验检疫备案号	3664100019
有效期	长期



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。

检验检测报告

报告编号： YQZC20200488

委托方： 江西宏之康科技有限公司

检品名称： 红外体温计

型号： HZK-801

检验类别： 注册检验 ()

注册补充检验 ()

其他检验 ()

江西省医疗器械检测中心



SHOT ON REDMI 7
AI DUAL CAMERA





合格证

CERTIFICATE OF QUALITY

产品名称: 医用红外线体温计

Product Name: Medical Infrared Thermometer

产品型号: HZK-801

Product Model: HZK-801

执行标准: YY0505-2012, GB9706.1-2007

Executive Standard: YY0505-2012, GB9706.1-2007

注册号: 赣械注准 20202070253

Registration Number: 20202070253

生产许可证号:

Production license No.:

生产批次号:

Production batch:

生产日期:

Production Date:

使用期限: 3 年

Period of Validity: 3 years

产品使用范围: 非接触测量体温

Product Range: Take temperature without contact

生产厂商: 江西宏之康科技有限公司

Manufacture: JIANGXI BIGHEALTHY TECH CO., LTD

生产地址: 江西省赣州市龙南县龙南经济技术开发区龙南镇第二工业小区 宏泰科技园 1 楼

Production Address: 1F, Hongtai Technology Park, No.2 Industrial Area, LONGNAN Economic and Development Area, LONGNAN Town, Ganzhou City, JIANGXI Province, China



Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

Jiangxi Bighealthy Tech Co., LTD
1F, Hongtai Technology Park, No.2 Industrial Area,
LONGNAN Economic and Development Area, LONGNAN
Town, Ganzhou City, JIANGXI Province, China. 341700

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen CCT Testing Technology Co., Ltd.



Owner/Operator Number: 10067936

Device Listing#: See next page

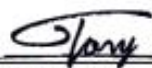
Listing No	Code	Device Name	Proprietary Name
D387234	FLL	Thermometer, electronic, clinical	infrared Thermometer, HZK-801 / HZK-802 / HZK-803 electric thermometer, HZK-901 / HZK-902 / HZK903

CCT 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. CCT 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. CCT 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, CCT is not affiliated with the U.S. Food and Drug Administration.

Shenzhen CCT Testing Technology Co., Ltd.
W: www.fda-test.com E: fda@fda-test.com
T: 400-8788-298 T: 86-755-36916737

Web: <http://www.fda.gov> Tel: 1-888-INFO-FDA (1-888-463-6332) e-mail: webmail@oc.fda.gov


Chief engineer
Issued: 04/07/2020
Expiration Date: 12/31/2020



FCC-VERIFICATION

NCT20012480XF1-1

This verification that the following designated product

Medical infrared thermometer

Model: HZK-801

(Other models please see the page 3 of the test report)

(Product Identification)

It is herewith confirmed and round to comply with the requirements set up by regulation for the evaluation of electromagnetic compatibility. This device complies with of the FCC rules, operation is subject to the following two conditions.

- 1) this device may not cause harmful interference and,
- 2) this device must accept any interference received, including interference that may cause undesired operation.

This declaration is the responsibility of the manufacturer/importer

Jiangxi hongzhikang technology co., LTD.

Second industrial community, Longnan town, Longnan economic and technological development zone, Longnan county, Ganzhou city, Jiangxi province.

Identification of regulation: 47 CFR Part 15 Subpart B Class B, Measurement Procedure: ANSI C63.4:2014. It is only valid in connection with the test report number: NCT20012480XF1-1.

TEST LABORATORY

This is the results of test that was carried out from the submitted type-samples of a product in conformity with the specification of the respective standards. The certificate holder has the right to fix the FCC-mark for EMI on the product complying with the inspection sample.



Authorized Signer: _____



Jack Dulles

Date: Mar. 20, 2020

This verification is only valid for the equipment and configuration described, in conjunction with the test data detailed above

Shenzhen NCT Testing Technology Co., Ltd.

Hotline: 400-8868-419 Http://www.nct-testing.cn

1&4 / F, No. B Building, Mianshang Younger Pioneer Park, Hangcheng Road,
Gushu Xixiang Street, Baoan District, Shenzhen

CERTIFICATE OF CONFORMITY

Certificate No. : NCT20012479XE1-1

Product Name : Medical infrared thermometer

Model No : HZK-801
(Other models please see the page 3 of the test report)

Applicant : Jiangxi hongzhikang technology co., LTD.
Address : Second industrial community, Longnan town, Longnan economic and technological development zone, Longnan county, Ganzhou city, Jiangxi province.

Manufacture : Jiangxi hongzhikang technology co., LTD.
Address : Second industrial community, Longnan town, Longnan economic and technological development zone, Longnan county, Ganzhou city, Jiangxi province.

Trademark : HZK

The above products have been tested by us with the listed standards and found in compliance with the EUROPEAN COUNCIL EMC DIRECTIVE 2014/30/EU. It is possible to use CE marking to demonstrative the compliance with this EMC directive.

Test standards:	Report(s) Number	Issued By	Issued Date
EN 61000-6-3:2007+A1:2011/AC2012	NCT20012479XE1-1	NCT	Mar. 20, 2020
EN 61000-3-2:2014			
EN 61000-3-3:2013			
EN 61000-6-1:2017			

This certificate of conformity is not transferable and based on an evaluation of a sample of the above mentioned product.



Date: Mar. 20, 2020

Signature: 

Shenzhen NCT Testing Technology Co., Ltd.

Hotline:400-8868-419

Http://www.nct-testing.cn

1&4 / F, No. B Building, Mianshang Younger Pioneer Park, Hangcheng Road, Gushu Xixiang Street, Baoan District, Shenzhen, Guangdong, China.

CERTIFICATE OF CONFORMITY

Certificate No. : NCT20012481XR1-1
Product Name : Medical infrared thermometer

Model No : HZK-801、HZK-802、HZK-803、HZK-805、HZK-806、
HZK-807、HZK-808、HZK-809、HZK-810
Trademark : 宏之康 HZK

Applicant : Jiangxi hongzhikang technology co., LTD
Address : Second industrial community, Longnan town, Longnan economic and technological development zone, Longnan county, Ganzhou city, Jiangxi province

Manufacturer : Jiangxi hongzhikang technology co., LTD
Address : Second industrial community, Longnan town, Longnan economic and technological development zone, Longnan county, Ganzhou city, Jiangxi province

The above products have been tested by us with the listed standards and found in compliance with the EUROPEAN COUNCIL ROHS DIRECTIVE 2011/65/EU AND AMENDMENT (EU)2015/863. It is possible to use CE marking to demonstrative the compliance with this ROHS directive.

Test standards:	Report(s) Number	Issued By	Issued Date
IEC62321-3-1:2013 IEC 62321-5:2013 IEC62321-4:2013+A1:2017 IEC62321-7-1:2015 IEC62321-7-2:2017 IEC62321-6:2015 IEC62321-8:2017	NCT20012481XR1-1	NCT	Mar. 21 2020

This certificate of conformity is not transferable and based on an evaluation of a sample of the above mentioned product.

RoHS

Date: Mar. 21, 2020

Signature: _____



Shenzhen NCT Testing Technology Co., Ltd.

Hotline: 86-755-27790922

Http://www.nct-testing.cn

1&4/ F, No. B Building, Mianshang Younger Pioneer Park, Hangcheng Road, Gushu Xixiang Street, Baoan District, Shenzhen, Guangdong, China.

MSDS Report

Prepared For : 申请商:	SHENZHEN DISHY HIGH TECHNOLOGY CO., LTD 深圳市迪生高科科技有限公司 9 building Shangcun Liandui Gongming Town Guangming New District Shenzhen China 中国广东省深圳市光明新区公明镇上村联队工业区 9 栋
Product Name: 产品名称:	Heavy Duty Battery 碱性电池
Model 型号:	R03P
Nominal Voltage: 标称电压	1.5V
Weight 重量:	6.5g
Dimension 尺寸 :	Max: $\Phi 10.5\text{mm} \times 44.5\text{mm}$ (D×H)
Prepared By : 编制单位:	Shenzhen NCT Testing Technology Co., Ltd. 深圳诺测检测技术有限公司 1 / F, No. B Building, Mianshang Younger Pioneer Park, Han gcheng Road, Gushu Xixiang Street, Baoan District, Shenzhen, Guangdong, China 中国广东省深圳市宝安区西乡街道固戍航城大道绵商青年创业 园 B 栋第 1 层
Report No. 报告编号:	NCT19049046XM1-1

Written by 编写: Carl Hsu

Approved by [Signature]

Inspected by 审核: Hedy Wong

Date 日期: 2020.01.02



NCT Technology

海运
By Sea

Shenzhen NCT Testing Technology Co., Ltd.

1 / F, No. B Building, Mianshang Younger Pioneer Park,
Hangcheng Road, Gushu Xixiang Street, Baoan District, Shen
zhen, Guangdong, China

货物运输条件鉴别报告书

Identification and Classification Report for Transport of Goods

非限制性

(Not subject to these Regulations)

货物名称:

碱性电池 R03P

Name of Goods:

Heavy Duty Battery R03P

委托单位:

深圳市迪生高科科技有限公司

Commission by:

SHENZHEN DISHY HIGH TECHNOLOGY CO., LTD

运输方式:

海运

Transportation:

Marine

深圳诺测检测技术有限公司
Shenzhen NCT Testing Technology Co., Ltd.



中国认可
检验
INSPECTION
CNAS IB0078

非限制性货物
NOT RESTRICTED

航空运输条件鉴别报告书

Identification and Classification Report for Air Transport of Goods

有效
2月31日

报告编号: PEKGZ20191213360GA750001

Issued No.:

签发日期:

Issued Date:

2020.01.01

委托单位: 深圳市迪生高科科技有限公司

Applicant: SHENZHEN DISHY HIGH TECHNOLOGY CO., LTD

物品名称: 碳性电池 R03P

Name of Goods: Heavy Duty Battery R03P

此报告本年度有效
有效期至2020年12月31日

北京迪捷姆空运技术开发有限公司
Beijing DGM Air Transport Technology Development Co.,Ltd.

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