

# Medical Infrared Thermometer

## Model: GP-300





产品名称：GP-300医用红外线体温计

内包装尺寸：170\*113\*55mm

外包装尺寸：570\*360\*360mm

每箱数量：60pcs

每箱重量：10KG

# 中华人民共和国医疗器械注册证（临）

注册证编号：黑械临注 20202070039

注册人名称	哈尔滨先德科技发展有限公司
注册人住所	哈尔滨市南岗区邮政街副 434 号 927 室
生产地址	哈尔滨市南岗区邮政街副 434 号 927 室
代理人名称	不适用
代理人住所	不适用
产品名称	医用红外体温计
型号、规格	GP-100、GP-200、GP-300、GP-400
结构及组成	医用红外体温计主要由红外温度传感器、显示单元、供电电路、测量电路、外壳组成。
适用范围	通过检测各年龄段人群额头的红外线能量来测量被测对象的体温。
附件	产品技术要求
其他内容	——
备注	

审批部门：黑龙江省药品监督管理局

批准日期：2020 年 3 月 13 日  
有效期至：2020 年 8 月 25 日





# Certificate of Compliance



No. 3J200331.HXTDC08

**Certificate's Holder:** Harbin Xiande Technology Development Co., Ltd.  
 Room 927, no.434, postal street, Nangang District, Harbin City, Heilongjiang Province

**Certification ECM Mark:**



**Product:** Medical infrared thermometer  
**Model(s):** GP-100/GP-200/GP-300/GP-400

**Verification to:** Standard:  
 EN 60335-1:2012/A13:2017,  
 EN 60335-2-63:2002, EN 61000-3-2:2014,  
 EN 61000-3-3:2013  
  
 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:



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](http://www.entecerma.it)

**Issuance date: 31 March 2020**

**Expiry date: 30 March 2025**

Reviewer  
 Technical expert  
 Amanda Payne

Approver  
 ECM Service Director  
 Luca Bedonni





# FDA REGISTRATION CERTIFICATE

**Fiscal year 2020**

This certificate that:

**HARBIN XIANDE TECHNOLOGY DEVELOPMENT CO., LTD.**  
No.434, Youzheng Street, Nangang District, Harbin City, Heilongjiang, 150006, CHINA

**Owner/Operator Number:10072274**

**Device Listing#:**

Listing No.	Code	Device Name	Proprietary Name
D397584	FQZ	THERMOMETER, CLINICAL COLOR CHANGE	Medical infrared thermometer, GP-100,GP-200,GP-300,GP-400

**Issued: 04/28/2020**

**Expiration Date: 12/31/2020**



Tel: 1-888-INF-FDA(1-888-463-6332)

e-mail:webmail@oc.fda.gov

Web.: <http://www.fda.gov>



Shenzhen CTL Testing Technology Co., Ltd.  
Tel:+86-755-89486194 E-Mail:ctl@ctl-lab.com

## FCC SDoC Test Report

### FCC PART 15 Subpart B

<b>Report Reference No.....:</b>	<b>CTL2003214011-F</b>
<b>Compiled by</b> ( position+printed name+signature)..:	File administrators Bruce Zheng
<b>Name of the organization performing the tests</b> ( position+printed name+signature)..:	Technique principal Ivan Xie
<b>Approved by</b> ( position+printed name+signature)..:	Manager Tracy Qi
<b>Date of issue.....:</b>	Apr. 01, 2020
<b>Representative Laboratory Name.:</b>	<b>Shenzhen CTL Testing Technology Co., Ltd.</b>
<b>Address.....:</b>	Floor 1-A, Baisha Technology Park, No.3011, Shahexi Road, Nanshan District, Shenzhen, China 518055
<b>Test Firm.....:</b>	<b>Shenzhen CTL Testing Technology Co., Ltd.</b>
<b>Address.....:</b>	Floor 1-A, Baisha Technology Park, No.3011, Shahexi Road, Nanshan District, Shenzhen, China 518055
<b>Applicant's name.....:</b>	<b>Harbin Xiande Technology Development Co., Ltd.</b>
<b>Address.....:</b>	Room 927, no.434, postal street, Nangang District, Harbin City, Heilongjiang Province
<b>Test specification:</b>	
<b>Standard.....:</b>	<b>FCC PART 15 Subpart B</b>
<b>TRF Originator.....:</b>	Shenzhen CTL Testing Technology Co., Ltd.
<b>Master TRF.....:</b>	Dated 2011-01
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<b>Test item description.....:</b>	<b>Medical infrared thermometer</b>
<b>Trade Mark .....</b>	N/A
<b>Test voltage.....:</b>	DC 9V
<b>Result.....:</b>	<b>Pass</b>





## FCC Test Report

<b>Test Report No. :</b>	<b>CTL2003214011-F</b>	Apr. 01, 2020
		Date of issue

Equipment under Test : Medical infrared thermometer

Type / Model : GP-100

Listed Models : GP-200, GP-300, GP-400

**Applicant** : **Harbin Xiande Technology Development Co., Ltd.**

Address : Room 927, no.434, postal street, Nangang District, Harbin City, Heilongjiang Province

**Manufacturer** : **Harbin Xiande Technology Development Co., Ltd.**

Address : Room 927, no.434, postal street, Nangang District, Harbin City, Heilongjiang Province

<b>Test Result</b>	<b>Pass</b>
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The test report merely corresponds to the test sample.

It is not permitted to copy extracts of these test result without the written permission of the test laboratory.

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Registrant/Manufacturer: Harbin Suntech Technology Co., Ltd.

Office/Production Address: No. 434, Post Street, Nangang District, Harbin, Heilongjiang

Tel: 0451 - 86230781 Fax: 0451 - 86230795

After-sales service: Harbin Suntech Technology Co., Ltd.

Tel: 0451 - 86230781 Fax: 0451 - 86230795

Revision: V1.0 Revision date: March 20, 2020 Production date: Refer to the label

Registration Certificate: HXLZ No. 20202070039

Technical Requirements for Products: HXLZ No. 20202070039

Production License for Medical Devices: HSYJXSCX No. 20160028



### **1.Application Range**

Display the body temperature by measuring the forehead thermal radiation.

### **2.Product Composition:**

Thermometer is composed of infrared sensor, microprocessor, LCD, etc.

### **3.Caution, Contraindication & Warning**

Caution:

- 1.Please read this manual carefully before use.
- 2.The product operating environment temperature is between 10°C to 40°C, the best temperature is 25°C
- 3.Please do not use the product when the temperature is above 40°C or below 0°C.
- 4.Please do not place the product too close to charged object to avoid electric shock.
- 5.Please do not use the product when relative humidity is more than 80%.
- 6.Please do not place the product too close to the electromagnetic field (e.g. radio or mobile phone, etc.)
- 7.Please do not expose the product in the sun, or place the product close to the stove, even touching the water.
- 8.Please do not strike or drop the product off. Please do not use the product if it is damaged.
- 9.The hair, sweat on the forehead, the cap or the scarf will affect the accuracy of the measurement data.
- 10.Please make sure the measurement distance is less than 15 cm.
- 11.When the room temperature is changing rapidly, please wait 15-20 minutes and then use the product to get the accurate, stable and reliable data.
- 12.Please measure the temperature from the back of the earlobe if the forehead temperature does not display the body temperature normally due to the sweat or other reasons.
- 13.Please wipe the surface of the product gently with alcohol if it is dirty.
- 14.Please contact the distributor and do not try to repair it by yourself if it has any problems.

### **Contraindication**

The temperature has no Standard. Please consult with the doctor whether you have a fever or not.

## Warning

- ☒ Make sure to remove the hair and the sweat before measuring the temperature.
- ☒ Using the product cannot replace the diagnosis of the doctor.
- ☒ Please contact the distributor and do not try to repair it by yourself if it has any problems.
- ☒ The protection glass of the LCD frame is very important and fragile, please use it carefully.
- ☒ Please do not charge the non-rechargeable battery and place the battery in the sun.
- ☒ Please do not explode the product in the sun or the water.

## 4. Technical Index

Display Resolution	0.1°C
Accuracy	Body mode: $\pm 0.2^{\circ}\text{C}$
Measurement Range	Body mode: $32^{\circ}\text{C} \sim 42.5^{\circ}\text{C}$
Measurement Distance	1–3cm
Operating Temperature	$10^{\circ}\text{C} \sim 40^{\circ}\text{C}$
Operating Humidity	$\text{RH} \leq 85\%$
Power Source	DC 3v (2pcs x 1.5v AAA Battery)
Auto Power-off	8min
Size	149*95*44mm
Weight	106G (Not including battery)



### 5. Advice before Use

Infrared forehead thermometer has high requirement of the surrounding environment. The correct measurement method is the key to accurate measurement.

- (1) The product is an professional infrared forehead thermometer to measure the body temperature. The measurement temperature may be different due to differences of the body skins.
- (2) When the room temperature is changing rapidly, please wait 20 minutes and then use the product.
- (3) When the measured person is from the place where the temperature is very different from the measurement environment, please measure the temperature after staying in the measurement environment for at least 5 minutes.
- (4) The measured person's surrounding environment should be stable. Do not measure the temperature in the outlet of the fan or air condition.
- (5) Do not use the instrument outdoor or in the strong sunlight
- (6) Do not hold the front site of the thermometer when measuring.
- (7) The measurement site should not be hidden by the hair. If there is sweat, wipe it with the dry towel and then measure the temperature to avoid the inaccurate data.
- (8) When the forehead of patient with fever is cold packed, sweaty or applied by other measures, the measurement result will be lower. Please do not measure the temperature under these circumstances.
- (9) Different methods are applied and different temperature is obtained according to different sites of Body. Please find different temperature in the following table.

Sites of Body	Normal temperature
Anal Temperature	36.6°C ~ 38°C
Oral Temperature	35.5°C ~ 37.5°C
Axillary Temperature	34.7°C ~ 37.3°C
Ear Temperature	35.8°C ~ 38°C
Forehead Temperature	35.8°C ~ 37.8°C

## **6.Quick Use**

### **3.1 Install battery**

3.2 Place the new battery correctly before the first use and then measure the temperature.

3.3 The thermometer front site aiming at the forehead in the distance of 5-15cm, make sure that there is no hair, sweat, cosmetics or cap and press the measurement button.

3.4 Measure the earlobe when the environment is changing rapidly or there is sweat on the forehead. Make sure there is no hair, sweat, cosmetics or cap.

Attention: the measurement values are different due to different skin colors, depths, body sites, environment changes. This situation is normal. The reason is, the more the skin exploded, the more the temperature is affected.

## **7.Battery Replacement**

The product can be used for 4000 times when using the 9V battery. When the battery symbol flickering on the top right of the screen, the battery should be replaced as soon as possible because of low power.

(1) Open the battery cover and replace the battery. Pay attention to the positive and negative polarities. The product design has anti reverse device. Even if the battery is reversed, the product is not damaged. It will not work.

(2) Please do not use rechargeable battery. Use the disposable batteries, primary alkali battery will be better.

(3) The quiescent current is very low when the instrument does not work. But if the product is not used for a long time, take out the battery in case of battery leakage and product damage.

### **Attention:**

1. Pay attention to the battery polarity when replacing the battery. The product may be damaged if the battery is reversed.

2. If the product is not used for a long time, take out the battery in case of battery leakage and product damage.

3. When the battery has the situation of leakage or mildew, it is not allowed to be used.

4. Please do not place the battery close to the fire or in the fire in case of battery explosion.

5. Please do not store the battery in the high temperature or high humidity environment.

6. To avoid short circuit, please do not place the battery, coins, keys and other metals in the same pocket or other containers that may trigger short circuit.



## 8. Operating Instruction

### 3.1 Thermometer site description

- (1) Infrared sensor
- (2) Measurement port
- (3) LCD liquid crystal display screen
- (4) "+" button
- (5) "-" button
- (6) "M" button
- (7) Backlight button
- (8) Buzzer button
- (9) Measurement button
- (10) Battery cover
- (11) Handle

### 8.2 Operating steps

- (1) Set the thermometer in the measurement mode, long press the starting button, measure the temperature all the time. If you do not need to measure the temperature all the time, press the button and then release it.
- (2) The following of "LOG" on the bottom left of the screen is the counter. The counter value is a circulation from 1 to 32. The counter value is increased once for each effective measurement. When the counter value gets to 32, it will return to 1. If the measurement result is "L0" or "H0", it is invalid. The measurement result is not stored. The counter value will not be increased.
- (3) Historical data review. The data is recorded automatically for each measurement. The instrument can record at most 32 data. If you want to review the data, press "M" button and then press "+" button or "-" button. "-" displays the latest data and "+" displays the oldest data. Pressing "+" or "-" again can review the data circularly.



## **9.Button Instructions**

- (1) Pressing "M" button once can review historical data. Short pressing "+" button can review the next data while short pressing "-" button can review the last data. A total of 32 groups of historical data can be reviewed.
- (2) If the measurement result is "L0" or "H0", it is invalid. The measurement result is not stored. The counter value will not be increased.
- (3) Short pressing backlight button can turn on and turn off the backlight.
- (4) Short pressing buzzer button can turn on and turn off the sound.

## **10.Routine Maintenance**

Please operate the product according to the instructions if the following situations occur when using the product.

- (1) Outer dirt: Wipe the dirt with clean soft cloth or cotton swab soaked in medical alcohol. Medical alcohol can also disinfect. Pay attention to not too much water or alcohol, so as not to flow into the product and cause injury.
- (2) Inner dirt: The lens of the internal probe is the important component. Do not touch or press the lens to avoid the inaccurate measurement data. Wipe the lens surface with cotton swab soaked in 90% absolute alcohol when finding the lens are dirty.

Attention: Do not wipe the lens with 75% alcohol (There will be residual water mark) and do not wipe the lens with other chemical agent (The chemical agent will damage the lens).

- (3) Storage: Store the product in a dry, dark place, out of direct sunlight.

## **11.Question & Answer**

If you meet the following problems, please refer to the guidelines to solve the problems. If you still cannot solve the problems, please contact with after-sales service.

- (1) Screen display temperature is above 42.5° C.
- (2) Screen display temperature is below 32° C.
- (3) The temperature is a little higher. Do not hold the front site. Holding the probe will make the temperature a little higher.
- (4) Screen displays "HI"  
When the product is on "body mode", the measurement temperature is above 42.5° C, the screen will displays "HI". Check if the body gets in touch with outer heat source. If it does not, contact with after-sales service.

**(1)Screen displays “L0”**









When the product is on “ body mode” , the measurement temperature is below 32° C, the screen will displays “L0” . Check the reasons according to the following table. If the reason is not the following, please contact with after-sales service.

Display “L0” reason	Suggestions
There is hair or sweat when measuring	Make sure there is no shelter
Cold air blow the forehead	Make sure the air environment is stable.
The forehead is cold packed	Measure the temperature 10 minutes after cold pack
The measurement distance is too far.	The best measurement distance is 5-15cm and do not touch the skin when measuring.

**12.Screen displays “HI”**

When the product is on “ body mode” , the measurement temperature is above 42.5° C, the screen will displays “HI”

**12.Medical Device Symbol, Graphic and Abbreviation Description**

Symbol	Description	Symbol	Description
	BF model device		Fear rain
	Refer to attached files		No hand hook
	Refer to Operating Instruction		Fragile
	II type device		Upper

**13.Part list**

instruction manual, warranty card, certificate.t

## 14. Appendix EMC

### 14.1 Electromagnetic compatibility (EMC)

#### ⚠ Notice:

- This thermometer meets the EMC requirements of the YY0505 standard:

- The user shall install and use it according to the EMC information provided in the accompanying documents;

- Portable and mobile RF communication equipment may affect the performance of the thermometer, and please avoid strong electromagnetic interference during using, such as close to mobile phones, microwave ovens, etc;


- The guidance and manufacturer's statement are detailed in the attached table.

#### ⚠ Warns:

- The thermometer shall not be used close to or stacked with other equipment. Under this condition (if necessary), it shall be observed and verified that it can operate normally in its used configuration;

- In addition to the cables sold by the manufacturer of this thermometer as spare parts of internal components, the use of accessories and cables other than those specified may cause the emission increase or anti-interference decrease of the thermometer.

- Wireless transmission emission and reception frequency band: reception frequency band: 2403 - 2480MHZ, emission frequency band: 2403 - 2480MHZ

Radiation symbol: 

- Even if other devices meet the sending requirements of corresponding national standards, this thermometer may be interfered by other devices.

Table 1


Guidance and manufacturer's statement_ electromagnetic emission		
The thermometer is expected to be used in the electromagnetic environment specified below, and the buyer or user shall guarantee that it is used in this environment:		
Emission tests	Compliance	Electromagnetic environment- Guidance
RF emission GB 4824	1 group	This thermometer only uses RF energy for its internal function. Therefore, its RF emission is very low, and tiny possibility of interference to nearby electronic equipment
RF emission GB 4824	B grade	
Harmonic emission GB 17625.1	A group	This thermometer is suitable for use in all facilities, including domestic facilities and the public low-voltage power supply network directly connected to the domestic residence
Voltage fluctuation / flashing emission GB 17625.2	Qualified	



Table2

Guidance and manufacturer's statement of electromagnetic anti-interference			
The thermometer is expected to be used in the following specified electromagnetic environment, and the buyer or user shall ensure that it is used in this environment:			
Anti-interference tests	IEC 60601 test voltages	Qualified voltages	Electromagnetic environment- Guidance
Electrostatic discharge GB/T 17626.2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	The ground shall be wooden, concrete or ceramic tile, and if it is covered with synthetic material, the relative temperature shall be at least 30%
Electrical fast transient burst GB/T 17626.4	±2kV to power cord	±2kV to power cord	The network power supply shall have the quality of typical commercial or hospital environment
Surge GB/T 17626.5z	±1 kV line to line ±2 kV L-PEv	±1 kV line to line ±2 kV L-PEz	The network power supply should have the quality of typical commercial or hospital environment
Voltage sag, short-time interruption and voltage change on the power input line GB/T 17626.11	<5% UT continuous 0.5 cycles (above UT, >95% sag) 40 % UT continuous 5 cycles (above UT, 60% sag) 70 % UT continuous 25 cycles (above UT, 30% sag) <5% UT continuous 5s (above UT, >95% sag)	<5% UT continuous 0.5 cycles (above UT, >95% sag) 40 % UT continuous 5 cycles (above UT, 60% sag) 70 % UT continuous 25 cycles (above UT, 30% sag) <5% UT continuous 5s (above UT, >95% sag)	The network power supply should have the quality of typical commercial or hospital environment. If the user of this thermometer needs to operate continuously during power interruption, it is recommended that this thermometer be powered by a UPS or battery.
Power Frequency Magnetic Field (50/60Hz) GB/T 17626.8	3A m	3A/m, 50Hz, 60Hz (in case of 60Hz)	The field should have the level characteristic in the typical business or hospital environment
Notice: UT refers to the AC network voltage before applying the test voltage.			

Table 3

Guidance and manufacturer's statement of electromagnetic anti-interference			
The thermometer is expected to be used in the following specified electromagnetic environment, and the buyer or user shall ensure that it is used in this environment:			
Anti-interference tests	IEC 60601 test voltages	Qualified voltages	Electromagnetic environment- Guidance
<p>conducted RF 17626.6 GB/T</p> <p>RF radiation GB/T 17626.6</p>	<p>3 V (effective value) 150 kHz ~ 80 MHz</p> <p>3V/m 80 MHz ~2.5 GHz</p>	<p>3 V (effective value)</p> <p>3V/m</p>	<p>Portable and mobile RF communication equipment shall not be used closer to any part of this thermometer (including cables) than the recommended isolation distance. The distance is calculated by the formula corresponding to the transmitter frequency.</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \quad 80\text{MHz} \sim 800\text{MHz}$ $d = 2.3 \sqrt{P} \quad 800\text{MHz} \sim 2.5\text{GHz}$ <p>P—According to the maximum rated output power of the transmitter provided by the manufacturer, in watts (W); d—Recommended separation distance, unit (m) . The field strength of the fixed RF transmitter is determined by the survey of electromagnetic field, which should be lower than the compliance level in each frequency range. Interference may occur near equipment marked with the following symbol.</p> 
<p>Notice 1: In the frequency of 80MHz and 800MHz, the formula of higher frequency band is adopted.</p> <p>Notice 2: The guideline may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection of buildings, objects and human body.</p>			
<p>Fixed transmitters, such as base stations for wireless (cellular / cordless) telephones and ground mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, are theoretically unpredictable in field strength. In order to evaluate the electromagnetic environment of the fixed RF transmitter, the survey of electromagnetic field should be considered. If the measured field strength of the thermometer is higher than the above applicable RF compliance level, the thermometer shall be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as readjusting the direction or position of the thermometer.</p> <p>In the whole frequency range of 150kHz-80MHz, the field strength should be lower than 3V / m.</p>			

**Table 4**

Recommended isolation distance between portable and mobile RF communication equipment and this thermometer			
The thermometer is expected to be used in the electromagnetic environment with controlled RF radiation disturbance. According to the maximum rated output power of the communication equipment, the buyer or user can prevent the most magnetic interference by maintaining the minimum distance between portable and mobile RF communication equipment (transmitter) and the thermometer as recommended below.			
Rated maximum output power of transmitter W	Isolation distance corresponding to different frequencies of transmitter/m		
	150 kHz~ 80 MHz $d = 1.2\sqrt{P}$	80MHz ~ 800MHz $d = 1.2\sqrt{P}$	800MHz ~ 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.78
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance D, in meters (m), can be determined by the formula in the corresponding frequency column of the transmitter, where p is the maximum rated output power of the transmitter provided by the manufacturer, in watts (W).

Notice : 1: At the frequencies of 80MHz and 800MHz, the formula of higher frequency band is adopted.

Notice: 2: The guideline may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human body.