Bingzun Infrared Thermometer

Henan Bingzun Industrial Co., Ltd

Brand Name: Bing Zun

Model: BZ-R6

Features:

- FDA Certificate
- Class I Medical Device(lowest risk)
- General Hospital Use
- 510K Exempt
- CE Certificate
- ISO Certificate
- FCC Certificate

Product Pictures

Henan Bingzun Industrial Co., Ltd

Bing Zun

1 second

Temperature measurement

Infrared Thermometer R6

Non-contact Infrared Thermometer

TEMPERATURE I INSTANT I ACCURATE

Bing Zun Infrared Thermometer

User Manual

Product certificate

Product name: Infrared thermometer

Model number: R6

Product grade: Qualified product

Executive standard: GB/T 2015-2458

Production date:

Henan Bingzun Industrial Co., Ltd

Address: 10 meters west to the south of Guihua Villa, Xin'an Industry Cluster District, Luoyang City, Henan Province, China

Bing Zun Infrared Thermometer

Product Packaging

BOX*1
THERMOMTER*1
USER MANUAL*1
PRODUCT CERTIFICATE*1

Master Case Packaging

40PC/CTN
CARTON SIZE:

- 49.5 * 40.6 * 29 CM
- 19.5 * 16.0 * 11.5 INCH

NET WEIGHT: 6.12KG/13.5LB/CTN
GROSS WEIGHT: 7.02KG/15.5LB/CTN


40 PCS


Henan Bingzun Industrial Co., Ltd
Bing Zun
1second
Temperature measurement
Infrared Thermometer
R6
Non-contact Infrared Thermometer
TEMPERATURE I INSTANT I ACCURATE

Product Spec Sheet

BINGZUN BZR6

Delicate, efficient and convenient

Product name	Medical infrared thermometer	
Product model	E1501	
Screen specification	4 * 14 (TN full transparent positive display, 28.5mm * 34.3mm * 2.8mm)	
Probe type	Tts-m5	
product type	Human body temperature measuring device	
Product weight	100g (without battery)	
Measuring distance	3CM-5CM	
Measurement accuracy	±0.2° C(0.5° F)	
Automatic shut off	About 20s	
Measuring time	0.5s	
Supply voltage	DC 3V (2 No.7 alkaline batteries / in series)	
Frequency of use	Press more than 100000 times	
Show exact digits	0.1° C (0.1° F)	
Storage temperature	-20-55 degrees C	
Operating temperature	5 ° C ~ 40 ° C, optimal temperature 25 °	
Relative humidity	≤85%	
Temperature range	32.0-42.99C	
High measurement accuracy (using plug-in only ADC algorithm processing)	32~35.9° C (93.2~96.6° F)	±0.3° C(0.5° F)
	36~39° C (96.8~102.2° F)	±0.2° C(0.4° F)
	39~43° C (102.2~109.4° F)4	±0.3° C(0.5° F)

Product structure:

Delicate, efficient and convenient	
1.	Infrared sensor
2.	Liquid crystal (LCD) display
3.	Backlight on / off button
4.	Up button (view historical data)
5.	Down button (view historical data)
6.	Sound switch button
7.	Measuring switch
8.	Handle
9.	Battery cover

Reference temperature:

Measuring location	Normal temperature (° C)	Normal Fahrenheit (° f)
Anus	36.6~38	97.8~100.4
oral cavity	35.5~37.5	95.9~99.5
Armpit	34.7~37.3	94.4~99.1
Ear	35.8~38	96.4~100.4
forehead	36~37.2	97.4~98.4

Product Certificates

BINGZUN BZR6


FDA
APPROVED

Establishment Registration & Device Listing

New Search | Back To Search Results

Proprietary Name:	Non-contact Infrared Thermometer; BZ-R3, R5, R6, R7, R8, R9, R11
Classification Name:	THERMOMETER, CLINICAL COLOR CHANGE
Product Code:	FQZ
Device Class:	1
Regulation Number:	880.2900
Medical Specialty:	General Hospital
Registered Establishment Name:	HENAN BINGZUN LNDUSTRIAL CO., LTD
Owner/Operator:	Henan Bingzun Industrial Co., Ltd
Owner/Operator Number:	10073151
Establishment Operations:	Manufacturer

FDA Class I medical device:
Device with lowest risk
to the patient and/or user
Pregnancy and Baby Safe

Product Classification

New Search | Back to Search Results

Device	Thermometer, Clinical Color Change
Regulation Description	Clinical color change thermometer.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	FQZ
Premarket Review	Gastrorenal, ObGyn, General Hospital, and Urology Devices (OHT3) Drug Delivery and General Hospital Devices, and Human Factors (DHT3C)
Submission Type	510(K) Exempt
Regulation Number	880.2900
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

510(K) Exempt:
No 510K Needed
No Pre-market Review Need

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

Recognized Consensus Standard

- 6-70 ASTM E825-98 (Reapproved 2016)
  Standard Specification for Phase Change-Type Disposable Fever Thermometer for Intermittent Determination of Human Temperature

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

CE CERTIFICATE

United testing

Certificate
Of
Compliance

Certificate Number:UNIA20040907EC-01

Applicant	:	**Henan BingZun Industrial Co., Ltd** 50 meters next to the south of Guihua Villa, Xin'an Industry Cluster District, Luoyang City, Henan Province, China
Manufacturer	:	**Henan BingZun Industrial Co., Ltd** 50 meters next to the south of Guihua Villa, Xin'an Industry Cluster District, Luoyang City, Henan Province, China
Product	:	Non-contact Electronic Thermometer
Trade Name	:	Bingzun, Cry, Yostand, Rainbow+
M/N	:	BZ-R6, R3, R5, R6, R7, R8, R9, R11, R12, R13, ET01, ET03, ET05, TWQ-01, Z3, Z5, Z6

Test Standard: EN 61326-1:2013

The EUT described above has been tested by us with the listed standards and found in compliance with the council EMC Directive 2014/30/EU. It is possible to use CE marking to demonstrate the compliance with EMC Directive.
The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production. It is only valid in connection with the test report number: UNIA20040907ER-01.

SHENZHEN UNITED TESTING TECHNOLOGY CO., LTD.

2020-04-22
Date of issue

Hoffer Lau

CE

Shenzhen United Testing Technology Co., Ltd.
2F, Annex Bldg, Jiahuangyuan Tech Park, #365 Baotian 1 Rd, Tiegang Community, Xixiang Str, Bao'an District, Shenzhen, China
Tel:+86-755-86180996 Fax:+86-755-86180156
http://www.uni-lab.hk E-mail:hofferlau@uni-lab.hk

FCC CERTIFICATE

United testing

SUPPLIER'S DECLARATION OF CONFORMITY

Certificate Number: UNIA20040905EC-01

We Hereby, Declare that the essential requirements set out in the 47 CFR Sections 2.906 of FCC, have been fully fulfilled on our product with indication below:

Applicant's Info

Company	:	Henan BingZun Industrial Co., Ltd
Address	:	50 meters next to the south of Guihua Villa, Xin'an Industry Cluster District, Luoyang City, Henan Province, China

Product Info

Product Name	:	Non-contact Electronic Thermometer
Model No.	:	BZ-R6, R3, R5, R6, R7, R8, R9, R11, R12, R13, ET01, ET03, ET05, TWQ-01, Z3, Z5, Z6
Trade Mark	:	Bingzun, Cry, Yostand, Rainbow+

Applied Standard

Standards	Report No.
E-CFR Title 47 Part 15 Subpart B	UNIA20040905ER-01

Responsibilities and obligations

Strictly follow the FCC rules of 2.906, 2.908, 2.909.

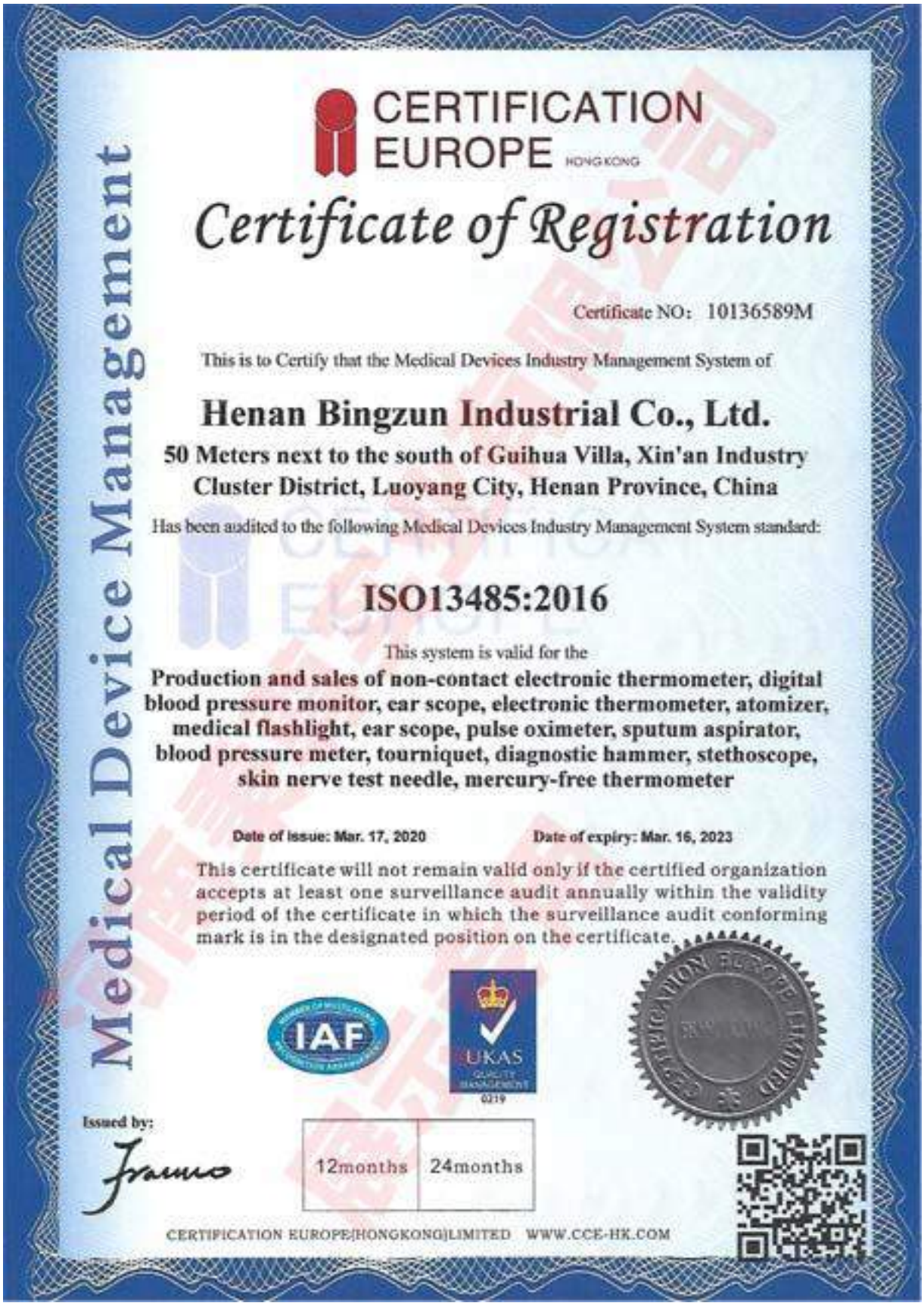
Responsible party in US.

Company:	Email:	Signature: _____
Address:	Tel:	
Contact person (print name):	Fax:	Date: _____

Test Firm Used to Take Measurements

Name:Shenzhen United Testing Technology Co., Ltd.
Address:#365 Baotian 1 Rd, Xixiang Str, Bao'an District, Shenzhen, Guangdong, China
Contact Name:Mr Liu ze
Tel:+86-755-86180996
Fax:+86-755-86180156
Email:hofferlau@uni-lab.hk
Designation No.:CN1227
FRN:0027159896

ISO13485:2016



CERTIFICATION EUROPE HONG KONG

Medical Device Management

Certificate of Registration

Certificate NO: 10136589M

This is to Certify that the Medical Devices Industry Management System of

Henan Bingzun Industrial Co., Ltd.

50 Meters next to the south of Guihua Villa, Xin'an Industry Cluster District, Luoyang City, Henan Province, China

Has been audited to the following Medical Devices Industry Management System standard:

ISO13485:2016

This system is valid for the

Production and sales of non-contact electronic thermometer, digital blood pressure monitor, ear scope, electronic thermometer, atomizer, medical flashlight, ear scope, pulse oximeter, sputum aspirator, blood pressure meter, tourniquet, diagnostic hammer, stethoscope, skin nerve test needle, mercury-free thermometer

Date of issue: Mar. 17, 2020 **Date of expiry: Mar. 16, 2023**

This certificate will not remain valid only if the certified organization accepts at least one surveillance audit annually within the validity period of the certificate in which the surveillance audit conforming mark is in the designated position on the certificate.

IAF

UKAS QUALITY MANAGEMENT 0219

Issued by:

Franco

12months	24months

CERTIFICATION EUROPE[HONGKONG]LIMITED WWW.CCE-HK.COM

Test Report

- **EMC TEST REPORT**
- **CHINA MEDICAL DEVICE TEST REPORT**

EMC TEST REPORT

Product:	Non-contact Electronic Thermometer
Trade Name:	Bingzun, Cry, Yostand, Rainbow+
Model Name:	BZ-R6
Serial Model:	R3, R5, R6, R7, R8, R9, R11, R12, R13, ET01, ET03, ET05, TWQ-01, Z3, Z5, Z6
Report No.:	UNIA20040907ER-01

Prepared for

Henan Bingzun, Cry, Yostand, Rainbow+ Industrial Co., Ltd

50 meters next to the south of Guihua Villa, Xin'an Industry Cluster District, Luoyang City, Henan Province, China

Prepared by

Shenzhen United Testing Technology Co., Ltd.

2F, Annex Bldg, Jiahuangyuan Tech Park, #365 Baotian 1 Rd, Tiegang Community, Xixiang Str, Bao'an District, Shenzhen, China

TEST RESULT CERTIFICATION

Applicant's name..... :	Henan Bingzun, Cry, Yostand, Rainbow+ Industrial Co., Ltd
Address..... :	50 meters next to the south of Guihua Villa, Xin'an Industry Cluster District, Luoyang City, Henan Province, China
Manufacture's Name..... :	Henan Bingzun, Cry, Yostand, Rainbow+ Industrial Co., Ltd
Address..... :	50 meters next to the south of Guihua Villa, Xin'an Industry Cluster District, Luoyang City, Henan Province, China

Product description

Product name..... :	Non-contact Electronic Thermometer
Trade Mark..... :	Bingzun, Cry, Yostand, Rainbow+
Model and/or type reference . :	BZ-R6, R3, R5, R6, R7, R8, R9, R11, R12, R13, ET01, ET03, ET05, TWQ-01, Z3, Z5, Z6
Standards..... :	EN 61326-1:2013

This device described above has been tested by Shenzhen United Testing Technology Co., Ltd., and the test results show that the equipment under test (EUT) is in compliance with the EMC Directive 2014/30/EU requirements. And it is applicable only to the tested sample identified in the report.

This report shall not be reproduced except in full, without the written approval of UNI, this document may be altered or revised by Shenzhen United Testing Technology Co., Ltd., personnel only, and shall be noted in the revision of the document.

Date of Test..... :

Date (s) of performance of tests..... :	Mar. 13, 2020 ~ Mar. 22, 2020
Date of Issue..... :	Mar. 22, 2020
Test Result..... :	Pass

Prepared by: Bob Liao

Bob Liao/Editor

Reviewer: Kahn Yang

Kahn yang/Supervisor

Approved & Authorized Signer: liuze

Liuze/Manager

Table of Contents Page

1 TEST SUMMARY

TEST RESULTS

Test procedures according to the technical standards:

EMC Emission				
Standard	Test Item	Limit	Judgment	Remark
EN 61326-1:2013	Conducted Emissions From The AC Mains Power Ports	Class B	N/A	
	Radiated Emissions	Class B	PASS	NOTE (1)
EN 61000-3-2:2014	Harmonic Current Emission	——	N/A	NOTE (2)
EN 61000-3-3:2013	Voltage Fluctuations & Flicker	——	N/A	
EMC Immunity				
Section EN 61326-1:2013	Test Item	Performance Criteria	Judgment	Remark
EN 61000-4-2:2009	Electrostatic Discharge	B	PASS	
EN 61000-4-3:2006 +A1:2008+A2:2010	RF Electromagnetic Field	A	PASS	
EN 61000-4-4:2012	Fast Transients	B	N/A	
EN 61000-4-5:2014 /A1:2017	Surges	B	N/A	
EN 61000-4-6:2014 /AC:2015	Injected Current	A	N/A	
EN 61000-4-8:2010	Power Frequency Magnetic Field	A	N/A	
EN 61000-4-11:2004 /A1:2017	Volt. Interruptions Volt. Dips	B / B / C / C	N/A	NOTE (3)

Note:

(1) If the highest frequency of the internal sources of the EUT is less than 108 MHz, the measurement shall only be made up to 1 GHz.
If the highest frequency of the internal sources of the EUT is between 108 MHz and 500 MHz, the measurement shall only be made up to 2 GHz.
If the highest frequency of the internal sources of the EUT is between 500 MHz and 1GHz, the measurement shall only be made up to 5 GHz.
If the highest frequency of the internal sources of the EUT is above 1 GHz, the measurement shall be made up to 5 times of the highest frequency or 6 GHz, whichever is less.

(2) The power consumption of EUT is less than 75W and no Limits apply.

(3) Voltage Dip: 100% reduction – Performance Criteria B
Voltage Dip: 100% reduction – Performance Criteria B
Voltage Dip: 30% reduction – Performance Criteria C
Voltage Interruption: 100% Interruption – Performance Criteria C

(4) For client's request and manual description, the test will not be executed.

(5) "N/A" denotes test is not applicable in this Test Report.

TEST FACTORY

Test Firm : Shenzhen United Testing Technology Co., Ltd.

Address : 2F, Annex Bldg, Jiahuangyuan Tech Park, #365 Baotian 1 Rd, Tiegang Community, Xixiang Str, Bao'an District, Shenzhen, China

The testing quality ability of our laboratory meet with "Quality Law of People's Republic of China" Clause 19.The testing quality system of our laboratory meets with ISO/IEC-17025 requirements. This approval result is accepted by MRA of APLAC.

Our test facility is recognized, certified, or accredited by the following organizations:

A2LA Certificate Number: 4747.01

The EMC Laboratory has been accredited by A2LA, and in compliance with ISO/IEC 17025:2017 General Requirements for testing Laboratories.

FCC Registration Number: 674885

The EMC Laboratory has been registered and fully described in a report filed with the (FCC) Federal Communications commission.

IC Registration Number: 21947

The EMC Laboratory has been registered and fully described in a report filed with the (IC) Industry Canada.

MEASUREMENT UNCERTAINTY

The reported uncertainty of measurement y ± U, where expended uncertainty U is based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95 %.

A. Conducted Measurement:

Test Site	Method	Measurement Frequency Range	U, (dB)	NOTE
UNI01	ANSI	9KHz ~ 150KHz	3.18	
		150 KHz ~ 30MHz	2.70	

B. Radiated Measurement:

Test Site	Method	Measurement Frequency Range	U, (dB)	NOTE
UNI02	ANSI	9KHz ~ 30MHz	2.50	
		30MHz ~ 200MHz	3.43	
		200MHz ~ 1000MHz	3.57	
		1GHz ~ 6 GHz	4.13	

2 GENERAL INFORMATION

2.1 GENERAL DESCRIPTION OF EUT

Equipment:	Non-contact Electronic Thermometer
Trade Mark:	Bingzun, Cry, Yostand, Rainbow+
Model Name:	BZ-R6
Serial No.:	R3, R5, R6, R7, R8, R9, R11, R12, R13, ET01, ET03, ET05, TWQ-01, Z3, Z5, Z6
Model Difference:	All model's the function, software and electric circuit are the same, only with a product color and model named different. Test sample model: BZ-R6.
Product Description:	The EUT is a Non-contact Electronic Thermometer. Operating frequency: N/A Connecting I/O port: N/A Based on the application, features, or specification exhibited in User's Manual, the EUT is considered as an ITE/Computing Device. More details of EUT technical specification, please refer to the User's Manual.
Power Source:	DC 3.0V

2.2 DESCRIPTION OF THE TEST MODES

To investigate the maximum EMI emission characteristics generates from EUT, the test system was pre-scanning tested base on the consideration of following EUT operation mode or test configuration mode which possible have effect on EMI emission level. Each of these EUT operation mode(s) or test configuration mode(s) mentioned above was evaluated respectively.

Pretest Mode	Description
Mode 1	Running

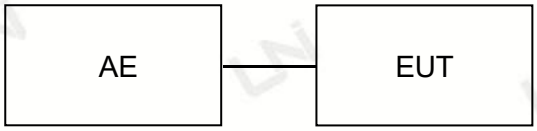
For Conducted Test	
Pretest Mode	Description
Mode 1	Running

For Radiated Test	
Pretest Mode	Description
Mode 1	Running

For EMS Test	
Pretest Mode	Description
Mode 1	Running

Note: The test modes were carried out for all operation modes (include link and idle).

2.3 DESCRIPTION OF TEST SETUP



Note: The EUT tested system was configured as upper figure, unless otherwise a special operating condition is specified in the following during the testing.

2.4 DESCRIPTION TEST PERIPHERAL AND EUT PERIPHERAL

The EUT has been tested as an independent unit together with other necessary accessories or support units. The following support units or accessories were used to form a representative test configuration during the tests.

Item	Equipment	Mfr/Brand	Model/Type No.	Note
E-1	Non-contact Electronic Thermometer	Bingzun, Cry, Yostand, Rainbow+	BZ-R6	EUT

Item	Shielded Type	Ferrite Core	Length	Note

Note:

1. The support equipment was authorized by Declaration of Confirmation.
2. For detachable type I/O cable should be specified the length in cm in『Length』column.
3. “YES” is means “shielded” “with core”; “NO” is means “unshielded” “without core”.

2.5 MEASUREMENT INSTRUMENTS LIST

Item	Equipment	Manufacturer	Model No.	Serial No.	Calibrated until
Conduction Emissions Measurement					
1	Conducted Emission Test Software	EZ-EMC	Ver.CCS-3A1-CE	N/A	N/A
2	AMN	Schwarzbeck	NNLK8121	8121370	2020.10.15
3	AMN	ETS	3810/2	00020199	2020.10.15
4	AAN	TESEQ	T8-Cat6	38888	2020.10.15
5	Pulse Limiter	CYBRTEK	EM5010	E115010056	2020.05.26
6	EMI Test Receiver	Rohde&Schwarz	ESCI	101210	2020.10.15
Radiated Emissions Measurement					
1	Radiated Emission Test Software	EZ-EMC	Ver.CCS-03A1	N/A	N/A
2	Horn Antenna	Sunol	DRH-118	A101415	2020.10.18
3	Broadband Hybrid Antenna	Sunol	JB1	A090215	2020.11.15
4	PREAMP	HP	8449B	3008A00160	2020.10.21
5	PREAMP	HP	8447D	2944A07999	2020.05.26
6	EMI Test Receiver	Rohde&Schwarz	ESBZ-R6	101891	2020.10.15
7	MXA Signal Analyzer	Keysight	N9020A	MY51110104	2020.10.15
8	Active Loop Antenna	Com-Power	AL-310R	10160009	2020.05.28
9	Horn Antenna	Schwarzbeck	BBHA9120D	9120D-1680	2020.05.28
10	Horn Antenna	A-INFOMW	LB-180400-KF	J211060660	2020.10.23
11	Loop Antenna	Beijing daze Technology	ZN30401	13015	2020.10.15
12	EM Clamp	Schwarzbeck	MDS21	03350	2020.10.20
Harmonic / Flicker Measurement					
1	Power Analyzer	California Instrumnets	PACS-1	X71719	2020.10.15
2	AC Power Source	California Instrumnets	5001ix	HK53570	2020.10.15
Electrostatic Discharge Test					
1	ESD Generator	EVERFINE	EMS61000-2A	P185811CA8371121	2020.10.17
RS Test					
1	Power Meter	Agilent	E4419B	QB4331226	2020.10.10
2	Power Sensor	Agilent	8481A	MY41092622	2020.10.10
3	Power Sensor	Agilent	8481A	US37296783	2020.10.10
4	Signal Generator	Agilent	N5182A	MY46240556	2020.10.10
5	Power Amplifier	MICOTOP	MPA-80-1000-250	1711489	2020.10.10
6	Power Amplifier	MICOTOP	MPA-1000-3000-75	1711488	2020.10.10
7	Power Amplifier	MICOTOP	MPA-3000-6000-50	MPA1706275	2020.10.10
8	Bilog Antenna	TESEQ	CBL6111D	34678	2020.10.10
9	Horn Antenna	Schwarzbeck	BBHA9120D	9120D-1680	2020.05.28

Item	Equipment	Manufacturer	Model No.	Serial No.	Calibrated until
Electrical Fast Transient / Burst Immunity Test					
1	EMS Test Control System	Shanghai Lioncel	SCU-614AS	SCU614S0160601	N/A
2	EFT/B Generator	Shanghai Lioncel	EFT-404S	EFT404S0160601	2020.10.15
Surge Test					
1	EMS Test Control System	Shanghai Lioncel	SCU-614AS	SCU614S0160601	N/A
2	Surge Generator	Shanghai Lioncel	LSG-506S	LSG506S0160601	2020.10.15
3	CDN	Shanghai Lioncel	CDN-532S	CDN532S0160601	2020.10.15
CS Test					
1	CS	SCHLODER	CDG-6000-25	126A1280/2014	2020.10.10
2	CDN	SCHLODER	CDN-M2+3	A2210275/2014	2020.10.10
3	EM Clamp	SCHLODER	EMCL-20	132A1283	2020.10.10
4	Attenuator	Nemtest	ATT-6DB-100	A100W224	2020.10.10
5	Audio Analyzer	R&S	UPL	100419	2020.10.10
6	Universal Radio Communication Tester	R&S	CMW500	117239	2020.10.10
7	Universal Radio Communication Tester	R&S	CMU200	111764	2020.10.10
8	Audio Analyzer	R&S	UPL	100689	2020.10.10
9	Audio Breakthrough Shielding Box	SKET	SB_ABT/C35	N/A	2020.10.10
10	Ear Simulator	SKET	AE_ABT/C35	N/A	2020.10.10
11	Mouth Simulator	SKET	AM_ABT/C35	N/A	2020.10.10
12	1KHz Standard Source	SKET	MSC_ABT/C35	N/A	2020.10.10
Power-frequency magnetic fields Test					
1	Magnetic Field Test System	Shanghai Lioncel	PMF801C-T	PMF801C-T0160701	2020.05.26
Voltage dips and interruptions Test					
1	Voltage SAG Simulator	Shanghai Lioncel	VDS-1101	VDS11010160601	2020.10.15
2	Adjustable Power Supply	Shanghai Lioncel	RGL-210	RGL2100151001	N/A

3 RADIATED EMISSIONS MEASUREMENT

3.1 RADIATED EMISSION LIMIT

Below 1000MHz:

Frequency (MHz)	Class A		Class B	
	10m	3m	10m	3m
	dBuV/m	dBuV/m	dBuV/m	dBuV/m
30~230	40	50	30	40
230~1000	47	57	37	47

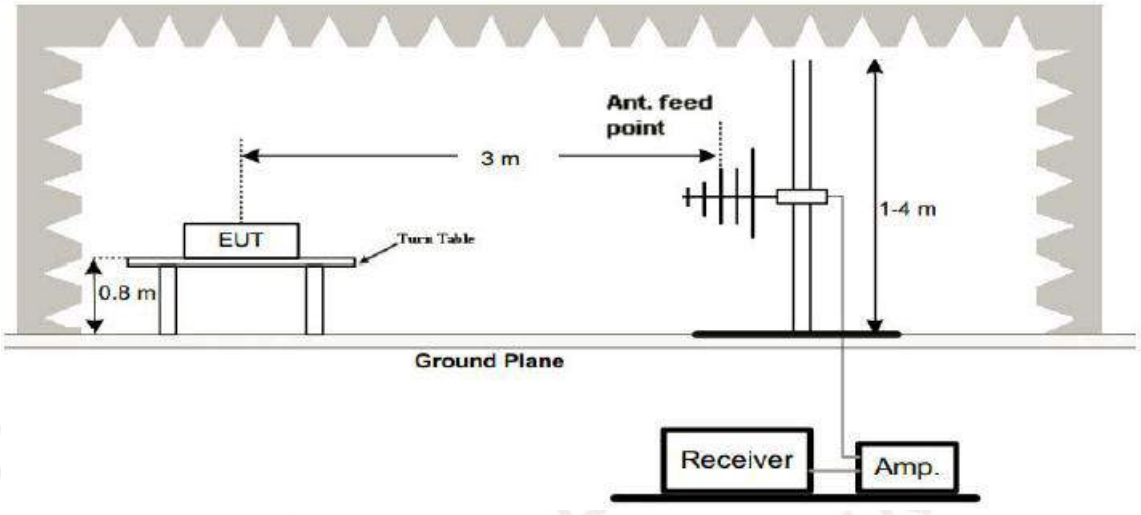
Above 1000MHz:

Frequency (MHz)	Class A		Class B	
	PK	AV	PK	AV
	dBuV/m	dBuV/m	dBuV/m	dBuV/m
1000~3000	76	56	70	50
3000~6000	80	60	74	54

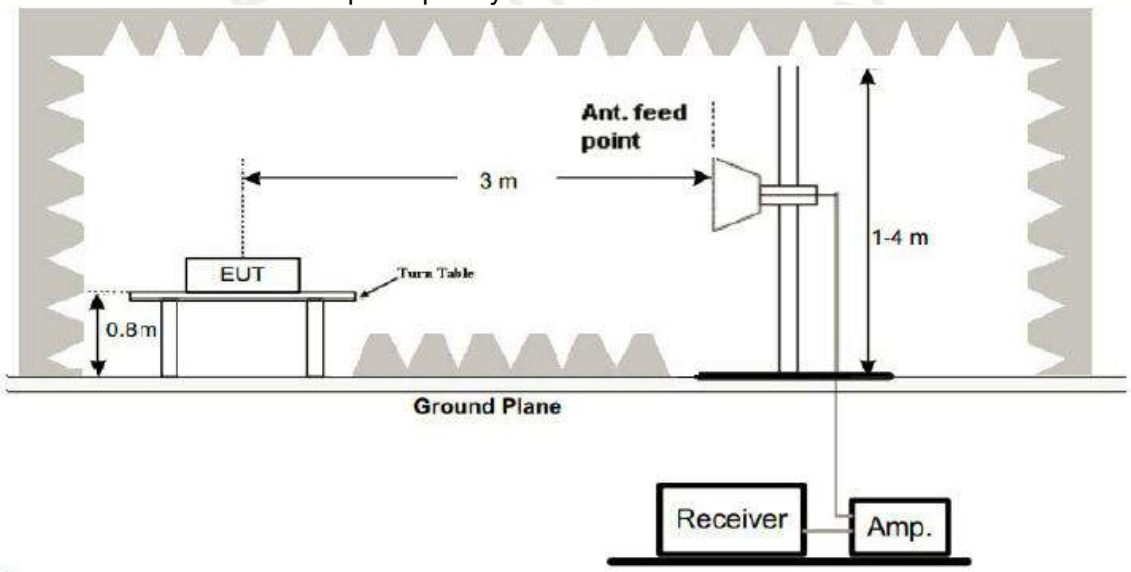
Note:
1. The tighter limit applies at the band edges.
2. Emission level (dBuV/m)=20log Emission level (uV/m).

3.2 TEST SETUP

1. Radiated Emission Test-Up Frequency Below 1000MHz



2. Radiated Emission Test-Up Frequency Above 1000MHz



3.3 TEST PROCEDURE

1. The EUT was placed on the top of a rotating table 0.8 meters above the ground at a 3 meter semi-anechoic chamber room. The table was rotated 360 degrees to determine the position of the highest radiation.
2. The EUT was set 3 meters away from the interference-receiving antenna, which was mounted on the top of a variable-height antenna tower.
3. The height of antenna is varied from 1 meter to 4 meters above the ground to determine the maximum value of the field strength. Both horizontal and vertical polarizations of the antenna are set to make the measurement.
4. For each suspected emission, the EUT was arranged to its worst case and then the antenna was tuned to heights from 1 meter to 4 meters and the rotatable table was turned from 0 degrees to 360 degrees to find the maximum reading.
5. The test-receiver system was set to quasi-peak detect function and specified bandwidth with maximum hold mode when the test frequency is below 1GHz.
6. For the actual test configuration, please refer to the related Item EUT Test Photos.

3.4 TEST RESULT

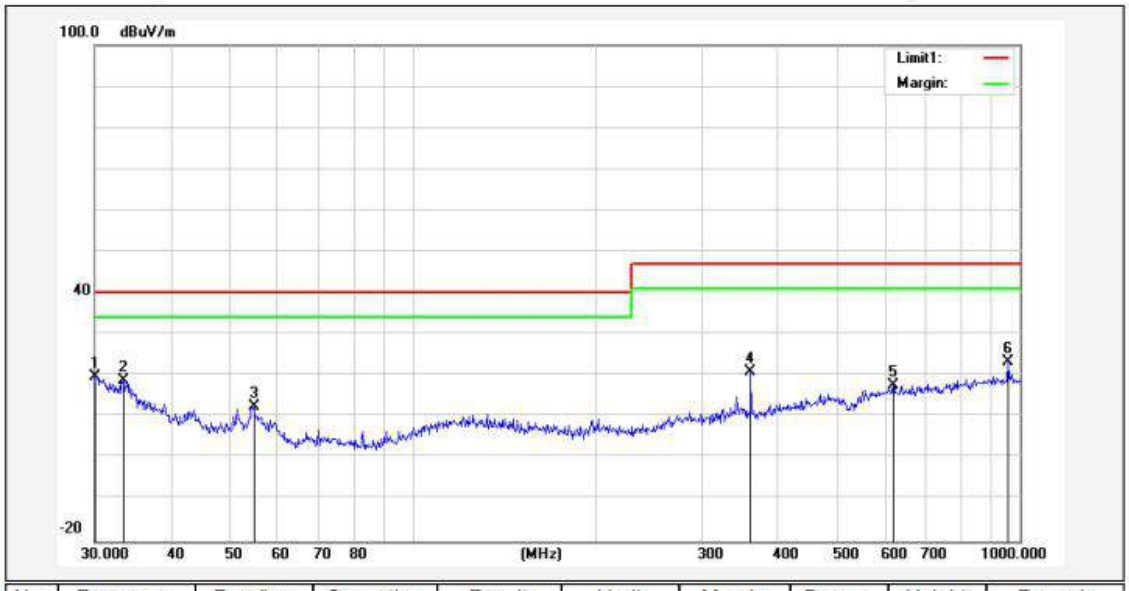
PASS

Temperature:	24℃	Relative Humidity:	48%
Test Voltage:	DC 3.0V	Pressure:	1010hPa
Test Mode:	Running	Polarization:	Horizontal

No.	Frequency (MHz)	Reading (dBuV)	Correction factor(dB/m)	Result (dBuV/m)	Limit (dBuV/m)	Margin (dB)	Degree (deg.)	Height (cm)	Remark
1*	30.2111	30.35	-7.31	23.04	40.00	-16.96			peak
2	54.4516	34.75	-21.12	13.63	40.00	-26.37			peak
3	124.5690	26.83	-16.52	10.31	40.00	-29.69			peak
4	452.7197	27.64	-12.26	15.38	47.00	-31.62			peak
5	607.7867	26.98	-9.43	17.55	47.00	-29.45			peak
6	955.4381	34.67	-6.10	28.57	47.00	-18.43			peak

Remark: Absolute Level = Reading Level + Factor, Margin = Absolute Level – Limit
Factor = Ant. Factor + Cable Loss – Pre-amplifier

Temperature:	24℃	Relative Humidity:	48%
Test Voltage:	DC 3.0V	Pressure:	1010hPa
Test Mode:	Running	Polarization:	Vertical



No.	Frequency (MHz)	Reading (dBuV)	Correction factor(dB/m)	Result (dBuV/m)	Limit (dBuV/m)	Margin (dB)	Degree (deg.)	Height (cm)	Remark
1*	30.1054	27.11	-7.23	19.88	40.00	-20.12			peak
2	33.4449	28.57	-9.85	18.72	40.00	-21.28			peak
3	54.8348	33.83	-21.16	12.67	40.00	-27.33			peak
4	360.4477	34.97	-14.05	20.92	47.00	-26.08			peak
5	618.5369	27.25	-9.56	17.69	47.00	-29.31			peak
6	955.4381	29.54	-6.10	23.44	47.00	-23.56			peak

Remark: Absolute Level = Reading Level + Factor, Margin = Absolute Level – Limit
Factor = Ant. Factor + Cable Loss – Pre-amplifier

4 EMC IMMUNITY TEST

4.1 STANDARD COMPLIANCE/SERVRITY LEVEL/CRITERIA

Tests Standard No.	TEST SPECIFICATION	Test Mode Test Ports	Perform Criteria
ESD IEC/EN 61000-4-2	8kV air discharge 4kV contact discharge	Direct Mode	B
	4kV HCP discharge 4kV VCP discharge	Indirect Mode	B
RS IEC/EN 61000-4-3	80 MHz to 1000 MHz, 1400 MHz to 2000 MHz, 2000 MHz to 2700 MHz, 1000Hz, 80%, AM modulated	Enclosure	A

4.2 GENERAL PERFORMANCE CRITERIA

According to EN 61326-1 standard, the general performance criteria as following:

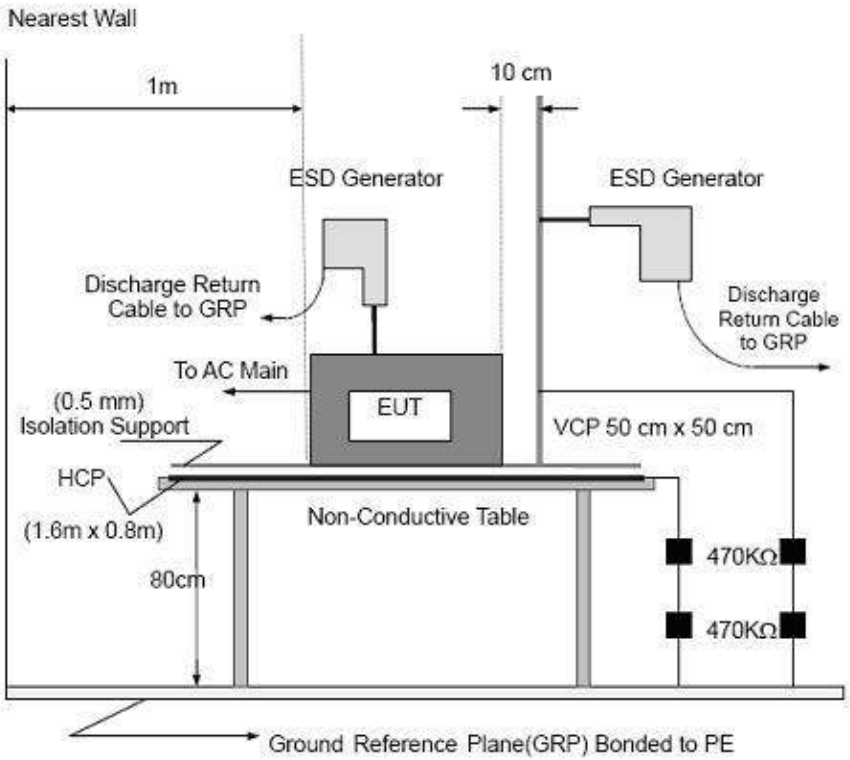
Criterion A	The equipment shall continue to operate as intended without operator intervention. No degradation of performance, loss of function or change of operating state is allowed below a performance level specified by the manufacturer when the equipment is used as intended. The performance level may be replaced by a permissible loss of performance. If the minimum performance level or the permissible performance loss is not specified by the manufacturer, then either of these may be derived from the product description and documentation, and by what the user may reasonably expect from the equipment if used as intended.
Criterion B	During the application of the disturbance, degradation of performance is allowed. However, no unintended change of actual operating state or stored data is allowed to persist after the test. After the test, the equipment shall continue to operate as intended without operator intervention; no degradation of performance or loss of function is allowed, below a performance level specified by the manufacturer, when the equipment is used as intended. The performance level may be replaced by a permissible loss of performance. If the minimum performance level (or the permissible performance loss), or recovery time, is not specified by the manufacturer, then either of these may be derived from the product description and documentation, and by what the user may reasonably expect from the equipment if used as intended.
Criterion C	Loss of function is allowed, provided the function is self-recoverable, or can be restored by the operation of the controls by the user in accordance with the manufacturer's instructions. A reboot or re-start operation is allowed.Information stored in non-volatile memory, or protected by a battery backup, shall not be lost.

5 ELECTROSTATIC DISCHARGE IMMUNITY TEST (ESD)

5.1 TEST SPECIFICATION

Basic Standard:	IEC/EN 61000-4-2
Discharge Impedance:	330 ohm / 150 pF
Required Performance:	B
Discharge Voltage:	Air Discharge：2kV/4kV/8kV (Direct) Contact Discharge：2kV/4kV (Direct/Indirect)
Polarity:	Positive & Negative
Number of Discharge:	Air Discharge: min. 20 times at each test point Contact Discharge: min. 200 times in total
Discharge Mode:	Single Discharge
Discharge Period:	1 second minimum

5.2 TEST SETUP



Note:

TABLE-TOP EQUIPMENT

The configuration consisted of a wooden table 0.8 meters high standing on the Ground Reference Plane. The GRP consisted of a sheet of aluminum at least 0.25mm thick. A Horizontal Coupling Plane (1.6m x 0.8m) was placed on the table and attached to the GRP by means of a cable with 940k total impedance. The equipment under test, was installed in a representative system as described in section 7 of IEC /EN 61000-4-2, and its cables were placed on the HCP and isolated by an insulating support of 0.5mm thickness. A distance of0.8-meter minimum was provided between the EUT and the walls of the laboratory and any other metallic structure.

FLOOR-STANDING EQUIPMENT

The equipment under test was installed in a representative system as described in section 7 of IEC/EN 61000-4-2, and its cables were isolated from the Ground Reference Plane by an insulating support of 0.1 meter thickness. The GRP was consisted of a sheet of aluminum that is at least 0.25mm thick, and extended at least 0.5 meters from the EUT on all sides.

5.3 TEST PROCEDURE

The test generator necessary to perform direct and indirect application of discharges to the EUT in the following manners:

1. Electrostatic discharges were applied only to those points and surfaces of the EUT that are accessible to users during normal operation The test was performed with at least ten single discharges on the pre-selected points in the most sensitive polarity.
   The time interval between two successive single discharges was at least 1 second.
   The ESD generator was held perpendicularly to the surface to which the discharge was applied and the return cable was at least 0.2 meters from the EUT.
   Contact discharges were applied to the non-insulating coating, with the pointed tip of the generator penetrating the coating and contacting the conducting substrate.
   Air discharges were applied with the round discharge tip of the discharge electrode approaching the EUT as fast as possible (without causing mechanical damage) to touch the EUT. After each discharge, the ESD generator was removed from the EUT and re-triggered for a new single discharge. The test was repeated until all discharges were complete.
   Vertical Coupling Plane (VCP):
   The coupling plane, of dimensions 0.5m x 0.5m, is placed parallel to, and positioned at a distance 0.1m from, the EUT, with the Discharge Electrode touching the coupling plane.
   The four faces of the EUT will be performed with electrostatic discharge.
   Horizontal Coupling Plane (HCP):
   The coupling plane is placed under to the EUT. The generator shall be positioned vertically at a distance of 0.1m from the EUT, with the Discharge Electrode touching the coupling plane.
   The four faces of the EUT will be performed with electrostatic discharge.
2. Air discharges at insulation surfaces of the EUT.
   It was at least ten single discharges with positive and negative at the same selected point.

5.4 TEST RESULT

Temperature:	22℃	Relative Humidity:	48%
Test Voltage:	DC 3.0V	Pressure:	1010hPa
Test Mode:	Running		

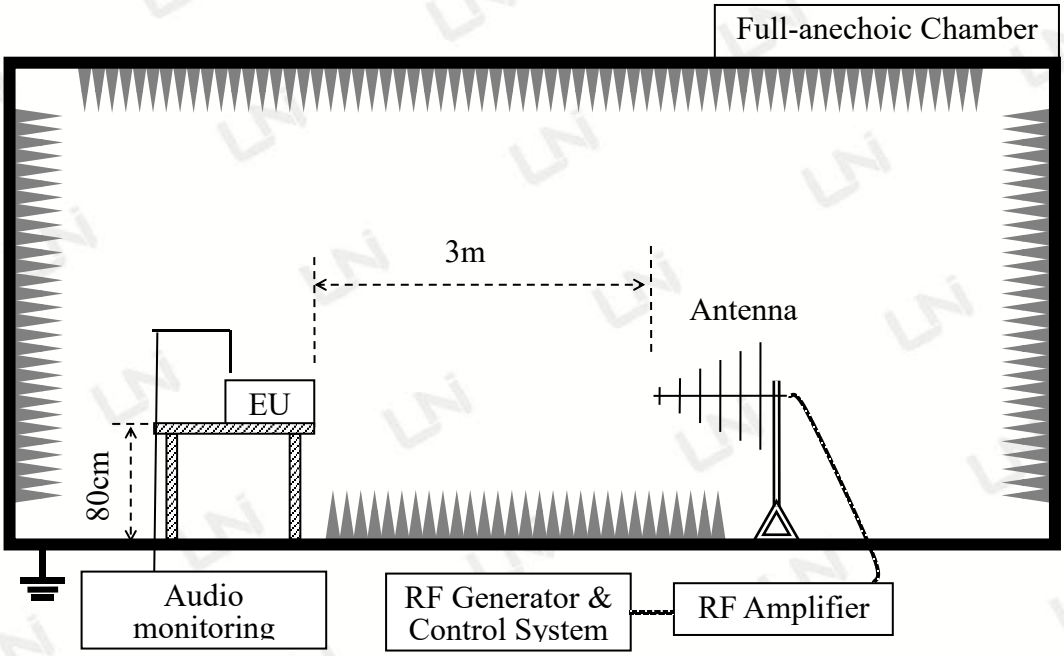
Mode	Air Discharge								Contact Discharge								Perform Criteria	Result
Test level (kV)	4		8		10		15		2		4		6		8			
Test Location	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-		
HCP									A	A	A	A					B	PASS
VCP									A	A	A	A						PASS
Slots	A	A	A	A														PASS
Surface	A	A	A	A														PASS

6 RADIATED, RADIO-FREQUENCY, ELECTROMAGNETIC FIELD IMMUNITY TEST (RS)

6.1 TEST SPECIFICATION

Basic Standard:	IEC/EN 61000-4-3
Required Performance:	A
Frequency Range:	80 MHz to 1000 MHz, 1400 MHz to 2000 MHz, 2000 MHz to 2700 MHz
Field Strength:	80 MHz to 1000 MHz: 3 V/m 1400 MHz to 2000 MHz: 3 V/m 2000 MHz to 2700 MHz: 1 V/m
Modulation:	1kHz Sine Wave, 80%, AM Modulation
Frequency Step:	1 % of fundamental
Polarity of Antenna:	Horizontal and Vertical
Test Distance:	3 m
Antenna Height:	1.5 m
Dwell Time:	1.5x 10^{-3} decade/s

6.2 TEST SETUP



Note:

TABLE-TOP EQUIPMENT

The EUT installed in a representative system as described in section 7 of IEC/EN 61000-4-3 was placed on a non-conductive table 0.8 meters in height. The system under test was connected to the power and signal wire according to relevant installation instructions.

FLOOR-STANDING EQUIPMENT

The EUT installed in a representative system as described in section 7 of IEC/EN 61000-4-3 was placed on a non-conductive wood support 0.1 meters in height. The system under test was connected to the power and signal wire according to relevant installation instructions.

6.3 TEST PROCEDURE

The EUT and support equipment, which are placed on a table that is 0.8 meter above ground and the testing was performed in a fully-anechoic chamber.
The testing distance from antenna to the EUT was 3 meters.
The other condition need as following manners:

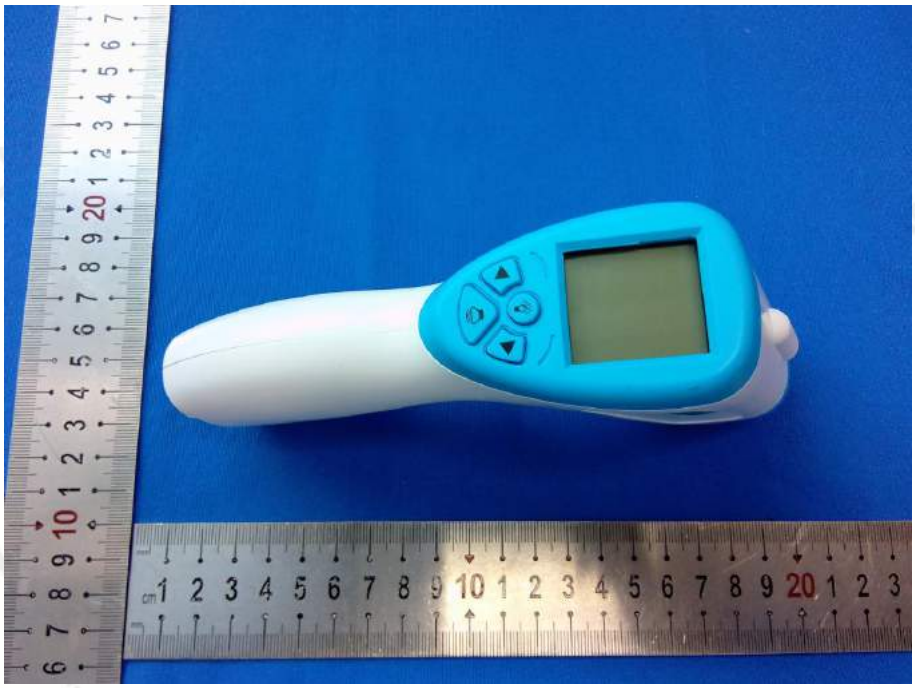
1. The frequency range is swept from 80 MHz to 1000 MHz, 1800 MHz, 2600 MHz, 3500 MHz, 5000 MHz, with the signal 80% amplitude modulated with a 1kHz sine wave. The rate of sweep did not exceed 1.5x 10^{-3} decade/s. Where the frequency range is swept incrementally, the step size was 1% of fundamental.
2. The dwell time at each frequency shall be not less than the time necessary for the EUT to be able to respond.
3. The test was performed with the EUT exposed to both vertically and horizontally polarized fields on each of the four sides.

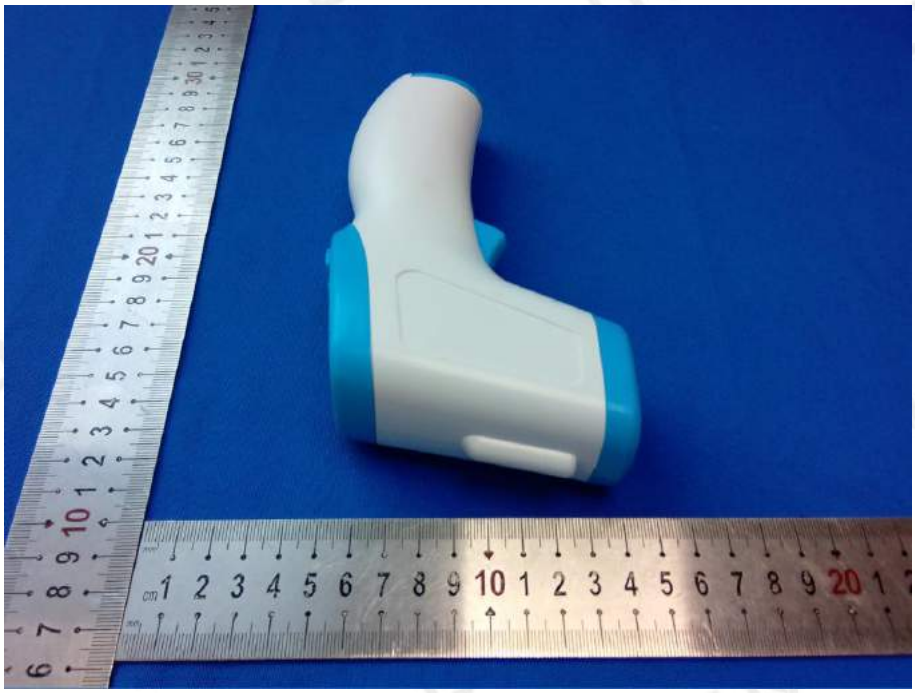
6.4 TEST RESULT

Temperature:	22℃	Relative Humidity:	48%
Test Voltage:	DC 3.0V	Pressure:	1010hPa
Test Mode:	Running		

Frequency Range (MHz)	RF Field Position	R.F. Field Strength	Azimuth	Perform Criteria	Result
80~1000	H / V	3 V/m (rms) AM Modulated 1000Hz, 80%	Front	A	PASS
			Rear		
			Left		
			Right		
1400~2000	H / V	3 V/m (rms) AM Modulated 1000Hz, 80%	Front	A	PASS
			Rear		
			Left		
			Right		
2000~2700	H / V	1 V/m (rms) AM Modulated 1000Hz, 80%	Front	A	PASS
			Rear		
			Left		
			Right		

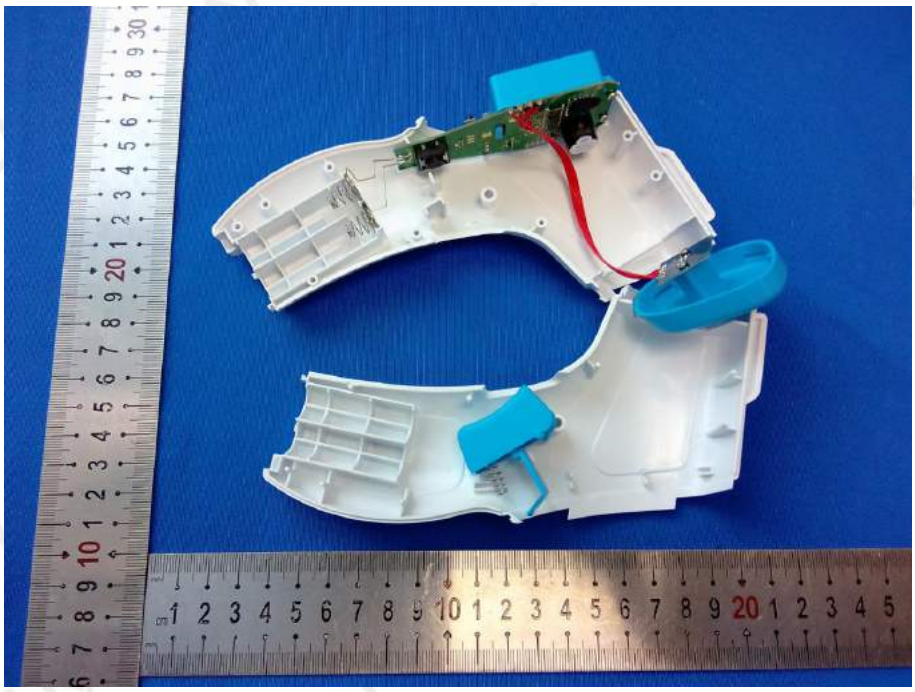
7 PHOTO OF EUT

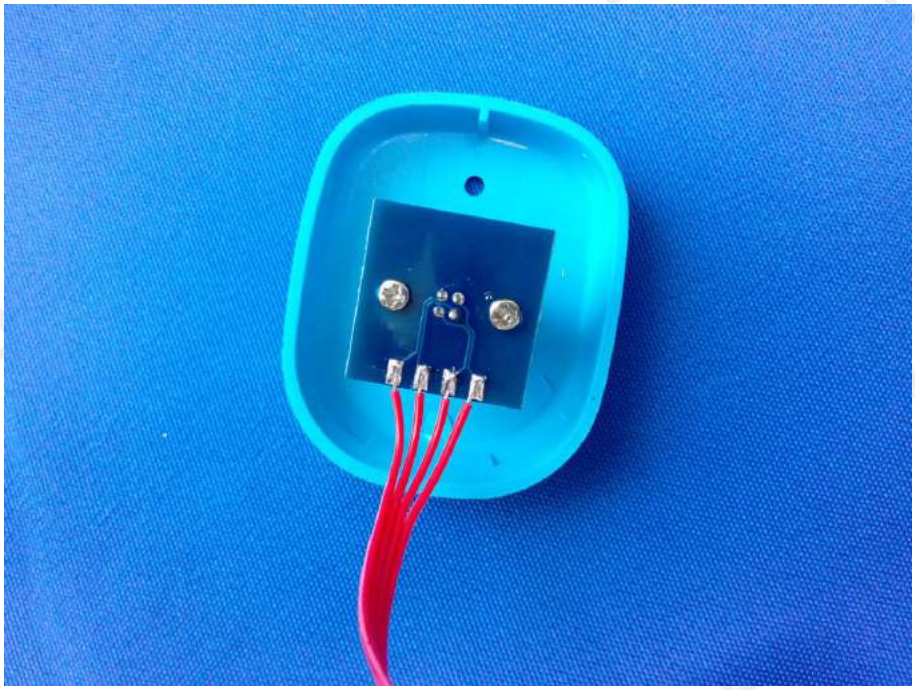


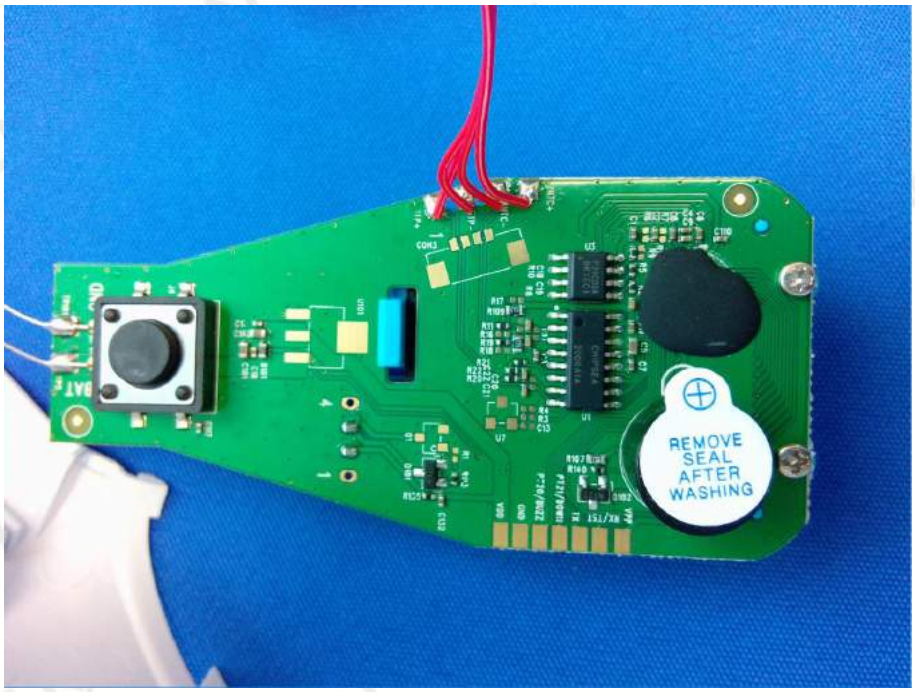



GP Super


Super
ALKALINE BATTERY
24A • LR03 • SIZE AAA • 1.5V






REMOVE
SEAL
AFTER
WASHING


DOWN

8 PHOTO OF TEST

End of Report

No.202001354(更)

河南省医疗器械检验所

检验检测报告

产品名称：红外额温计

检验类别：应急检验

委 托 方：河南秉尊实业有限公司

声 明

一、本检验检测报告仅对我单位接收到的样品负责。

二、本检验检测报告涂改增删无效，无“检验检测报告专用章”无效，无批准人签字无效。

三、复制报告未重新加盖检验机构检验检测报告专用章或检验单位公章无效。

四、本检验检测报告一式三份，二份交送检单位，一份由我单位存档。

五、对检验检测报告若有异议，应于规定期限内向我所提出书面申诉意见，逾期未提出异议的，视为认可检验检测结果。

六、未加盖CMA章的检验检测报告，仅用于医疗器械产品注册。

河南省医疗器械检验所

检验检测报告首页

报告编号：202001354(更)

样品编号：急20200293

样品名称	红外额温计	样品数量	3个
	送样（√） 抽样（ ）	规格型号	BZ-R6
委托方	河南秉尊实业有限公司		
生产地址	河南省洛阳市新安县产业集聚区桂花山庄南隔壁50米	生产批号	/
		生产日期	2020.3.6
标示生产单位	河南秉尊实业有限公司	产品编号	20200306003
受检单位	河南秉尊实业有限公司	有效期	5年
抽样单位	/	检验类型	应急检验
库存数量	/	样品状态	正常
抽样日期	/	收样日期	2020.03.12
抽样地点	/	检验地点	本检验所试验室
抽样单编号	/	检验日期	2020.03.12-2020.03.19
检验项目	部分项目		
检验依据	河南秉尊实业有限公司《红外额温计》产品技术要求		
检验结论	所检项目符合河南秉尊实业有限公司《红外额温计》产品技术要求的要求。 签发日期：2020年03月19日		
备注	1)报告中的“----”表示此项不适用，报告中“/”表示此项空白或未检。 2)附页：医疗器械产品技术要求预评价意见表。		

报告批准：

报告审核：

检　　验：

河南省医疗器械检验所

检验检测报告

样品编号：急20200293

红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
温度显示范围	2.1	33.0℃～43.0℃	符合要求	合格
最大允许误差	2.2	本产品在35.0℃～42.0℃的温度显示范围内，最大允许误差±0.2℃。	最大误差+0.2℃	合格
		本产品在35.0℃～42.0℃的温度显示范围外，最大允许误差±0.3℃。	最大误差+0.2℃	合格
		本产品在变化环境条件下，本产品在35.0℃～42.0℃的温度显示范围内最大允许误差应符合2.2.1的要求。	最大误差+0.2℃	合格
抗跌落性	2.3	本产品在正常使用时从垂直距离为1m高处以三次不同起始姿态自由跌落到一个硬质表面上后应符合2.2.1的要求。	符合要求	合格
指示单元	2.4	额温计显示屏的指示分辨率应为0.1℃。	符合要求	合格
		额温计显示屏上显示的数值高度应至少为4mm。	符合要求	合格
		a）电源低电压：当额温计实际供电电压低于2.4V±0.2V时，应有低电量显示或停止温度显示并关机； b）温度显示范围提示：当显示温度＜33.0℃时出现“Lo”提示；当显示温度＞43.0℃时出现“HI”提示； c）测量完成提示：额温计从开始到测量结束的时间在5秒内，在测量完成时听到“嘀”一声表示测量完成；	a）2.3V b）符合要求 c）符合要求	合格
		额温计应有额温测量模式和校准测量模式。	符合要求	合格
产品的清洁和消毒	2.5	额温计与人体额头接触的部分应有相应的清洁和消毒要求，并满足在清洁和消毒后，仍然符合2.2.1的要求，且其外壳上的标志不受影响。	符合要求	合格

河南省医疗器械检验所

检验检测报告

样品编号：急20200293

红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
自检功能	2.6	额温计在正常开机后应进入自检模式，自检完成之后进入待测状态。	符合要求	合格
自动关机功能	2.7	额温计在15s内无操作时应自动关机。	符合要求	合格
外观与结构	2.8	额温计的外形应端正，表面应光亮整洁，不得有锋棱、毛刺，明显的划痕、破损和变形；	符合要求	合格
		额温计按键上的文字和标志应准确、清晰、牢固；	符合要求	合格
		额温计显示屏显示的内容应无乱码、错码现象；	符合要求	合格
		额温计的功能按键应灵活可靠、紧固件应无松动。	符合要求	合格
记忆功能	2.9	额温计对测量结果具有记忆功能。	符合要求	合格
GB 9706.1-2007《医用电气设备第1部分：安全通用要求》				
识别、标记和文件	6			
设备或设备部件的外部标记	6.1	a)电网供电的设备，包括网电源部分的分离元件，应至少在设备的“主件”上具有“永久贴牢的”和“清楚易认的”标记	----	----
		b)内部电源设备，应至少在设备的“主件”上具有“永久贴牢的”和“清楚易认的”标记	符合要求	合格

河南省医疗器械检验所

检验检测报告

样品编号：急20200293

红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
设备或设备部件的外部标记	6.1	c)由特定电源供电的设备，不管该电源是否是设备的一部分，应至少在设备上具有“永久贴牢的”和“清楚易认的”标记。如果该特定电源不是设备的一部分，则设备使用说明书还应另外给出该特定电源的型式标记。如果涉及安全问题，应把该特定电源的型式标记永久性地标在设备的外部，并在使用说明书中加以说明	----	----
		d)如果设备的尺寸或外壳特征不容许将所规定的标记全部标上时，至少应标上6.1e）、f）、g）、1）和q）所规定的标记，而其余的标记应在随机文件中完整地记载。无法做标记之处，应在随机文件中详细写明	符合要求	合格
		e)制造商、供应者，声称设备符合本标准要求的制造商或供应者的名称和（或）商标	符合要求	合格
		f)型式标记	符合要求	合格
		g)与电源连接：	----	----
		——设备可连接的额定供电电压或电压范围	----	----
		——电源类别，如相数和电流类型	----	----
		h)电源频率（Hz）以Hz为单位的额定频率或额定频率范围	----	----
		j)输入功率	----	----
		k)网电源功率输出，设备的辅助网电源插座应标明最大容许输出值	----	----
		1)分类：		

河南省医疗器械检验所

检验检测报告

样品编号：急20200293

红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
设备或设备部件的外部标记	6.1	——若合适，作II类设备符号	----	----
		——用字母IP 后接上X及按GB4208中外壳对有害进液防护程度来区分的特征数字（1至8），作为防进液设备的符号；	----	----
		——对B型、BF型和CF型应用部分，按防电击程度分类标示应用部分类型的符号	B型应用部分	合格
		——若设备具有一个以上不同程度防护的应用部分，应在这些应用部分上，或者在相关输出段（连接点）或其附近清楚标上相应的符号	----	----
		——防除颤应用部分应采用相应的符号标识	----	----
		——如果患者电缆具有对心脏除颤器放电效应的防护，则应在靠近相应输出端的电缆上标记附录D，表D1 中的符号14	----	----
		m)运行模式。如果没有标记，可认为该设备适合连续运行	符合要求	合格
		n)熔断器，从设备外部能触及的熔断器，应在熔断器座旁标明其型号及标称	----	----
		p)输出：	----	----
		——额定输出电压、电流或功率（如适用）	----	----
		——输出频率（如适用）	----	----

河南省医疗器械检验所

检验检测报告

样品编号：急20200293

红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
设备或设备部件的外部标记	6.1	q)生理效应（符号和警告性说明）。会产生可能对患者和（或）操作者造成危险生理效应的设备，应有相应危险的适当标记，应标在明显位置，并保证在设备安装后仍能清楚可见	----	----
		若适合，对特殊危险符号，应采用GB/T5465.2所规定的符号。对非电离辐射应使用附录D表D2的符号8	----	----
		对其他危险，若无规定的符号可用时，应使用附录D 中表D1 的符号14	----	----
		r)AP/APG类设备。对标记的要求，见第38 章	----	----
		s)高电压端子装置。在设备外部不用工具便可触及到的高电压端子装置，应标以“危险电压”标记（见附录D中表D2的符号6）	----	----
		t)冷却条件。对设备冷却装置的要求（例如供水或供气），应作出标记	----	----
		u)机械稳定性。对具有有限的机械稳定性的设备的要求，见第24 章	----	----
		v)保护性包装		
		若在运输和贮存中要采取特别措施，在包装上应做出相应的标记	符合要求	合格
		如果过早地拆开设备或设备部件的包装会造成安全方面危险，则在包装上应做出相应标记	----	----
		设备或附件的无菌包装应有无菌标志	----	----
		y)接地端子	----	----

河南省医疗器械检验所

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红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
设备或设备部件的外部标记	6.1	——与电位均衡导线相连的端子，应标有附录D中表D.1的符号9	----	----
		——功能接地端应以附录D中表D.1的符号7做标记	----	----
		z)可拆卸的保护装置。	----	----
		如果设备具有需拆掉保护装置才能启动其它应用的特殊功能时，应在该保护装置上标明当该特殊功能不应用时应将它还原的标记。若有联锁装置时则不需要标记	----	----
		设备标记的耐久性试验	符合要求	合格
随机文件	6.8.1	概述：设备应附有至少包括使用说明书、技术说明书和供使用者查询的地址在内的文件	符合要求	合格
		若使用说明书和技术说明书是分开的，则在第5章中规定的所有适用的分类都应包含在两个说明书中	----	----
		如果制造商没有把6.1规定的所有标记永久贴牢在设备上，则应在完整无缺地包含在随机文件中	----	----
		警告性声明和（标在设备上的）警告性符号的解释应在随机文件中给出	符合要求	合格
使用说明书	6.8.2	a）一般内容：—使用说明书应说明设备的功能和预期用途	符合要求	合格

河南省医疗器械检验所

检验检测报告

样品编号：急20200293

红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
使用说明书	6.8.2	——使用说明书应提供能使设备按其技术条件运行的全部资料。它应包括各控制器、显示器和信号的功能说明。操作顺序、可拆卸部件及附件的装、卸方法及使用过程中消耗材料的更换等的说明	符合要求	合格
		—使用说明书应向使用者或操作者提供有关存在于该设备与其它装置之间的潜在的电磁干扰或其它干扰的资料，以及有关避免这些干扰的建议	符合要求	合格
		——如果使用别的部件或材料会降低最低安全度，应在使用说明书中对被认可的附件、可更换的部件和材料加以说明	----	----
		——使用说明书应向使用者和操作者详细说明由他们自己来进行的清洗、预防性检查和保养，以及保养的周期	符合要求	合格
		这类说明书应提供安全地执行常规保养的资料	符合要求	合格
		此外，使用说明书还应提出哪些部件应由其他人进行预防性检查和保养，以及适用的周期，但不必包括执行这种保养的具体细节	----	----
		—设备上的图形、符号、警告性声明和缩写，应在使用说明书中说明	符合要求	合格
		c）信号输入部分和信号输出部分：只打算将信号输入部分和信号输出部分与符合本标准要求的规定设备相连接时，应在使用说明书中予以说明	----	----

河南省医疗器械检验所

检验检测报告

样品编号：急20200293

红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
使用说明书	6.8.2	d）与患者接触部件的清洗、消毒和灭菌：在正常使用时要与患者接触的设备部件，使用说明书应包括有关可使用的清洗、消毒或灭菌方法的细节，或在必要时规定合适的消毒剂，并列出这些设备部件可承受的温度、压力、湿度和时间的限值	符合要求	合格
		e）带有附加电源的电网供电设备：对带有附加电源的电网供电设备，若其附加电源不能自动地保持在完全可用的状态，使用说明书应提出警告，规定应对该附加电源进行定期检查和更换	----	----
		如果某Ⅰ类设备既可接至供电网运行，也可改由内部电源运行，则使用说明书应明确提出：如果外部的保护导线在安装或其布线的完整性有疑问时，设备应由内部电源来运行	----	----
		f）一次性电池的取出：配有一次性电池的设备，除非不存在产生安全方面危险的风险，使用说明书中应有警告：若在一段时间内不可能使用设备时，应取出这些电池	符合要求	合格
		g）可充电电池：配有可充电电池的设备，在使用说明书中应有如何安全使用和保养的说明	----	----
		h）有特定供电电源或电池充电器的设备：使用说明书应规定特定电源或电池充电器需保证符合本标准要求	----	----
		j）环境保护：使用说明书应：——指明有关废弃物、残渣等以及设备和附件在其使用寿命末期时的处理的任何风险；	符合要求	合格

河南省医疗器械检验所

检验检测报告

样品编号：急20200293

红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
使用说明书	6.8.2	——提供把这些风险降至最小的建议	符合要求	合格
技术说明书	6.8.3	a）概述：技术说明书应提供为安全运行必不可少的所有数据。包括：——在6.1 中提到的数据；	符合要求	合格
		——设备的所有特性参数，包括显示值或能够看到的指示的范围，准确度和精确度	符合要求	合格
		除了使用说明书已包括的内容外，技术说明书还应指明为安装设备和将设备投入使用时要采取的一些特别措施和特别条件	----	----
		b）熔断器和其他部件的更换：——在不能根据设备的标称电流和运行模式来决定连接在永久性安装设备之外的电源电路中的熔断器型号和标称值时，所要求的熔断器型号和标称值至少应在技术说明书中予以指明	----	----
		——技术说明书应包括在正常使用时会损坏的可更换部件和（或）可拆卸部件的更换说明	----	----
		c）电路图、元器件清单等：技术说明书应声明供应者可将按要求提供电路图、元器件清单、图注、校正细则，或其它有助于使用者的合格技术人员修理由制造商指定可修理的设备部件所必需的资料	符合要求	合格
		d）运输和贮存环境限制条件：技术说明书应规定运输和贮存时的允许环境条件，这些条件在设备包装的外部应重复给出	符合要求	合格

河南省医疗器械检验所

检验检测报告

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红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
正常工作温度下的连续漏电流	19.3	对地漏电流	----	----
		正常状态：≤0.5mA	----	----
		单一故障状态：≤1mA	----	----
		外壳漏电流		
		正常状态：≤0.1mA	＜0.004mA	合格
		单一故障状态：≤0.5mA	＜0.004mA	合格
		患者漏电流 B型、BF型应用部分		
		正常状态：直流≤ 0.01 mA	＜0.004mA	合格
		正常状态：交流≤0.1mA	＜0.004mA	合格
		单一故障状态：直流≤ 0.05 mA	＜0.004mA	合格
		单一故障状态：交流≤0.5mA	＜0.004mA	合格
		患者漏电流 CF型应用部分	----	----
		正常状态：直流≤ 0.01 mA	----	----
		正常状态：交流≤0.01mA	----	----
		单一故障状态：直流≤0.05mA	----	----
		单一故障状态：交流≤ 0.05 mA	----	----

河南省医疗器械检验所

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红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
正常工作温度下的连续漏电流	19.3	B型应用部分 信号输入/出部分加网电压：≤5mA	----	----
		应用部分加网电压 BF型：≤ 5 mA	----	----
		应用部分加网电压 CF型：≤ 0.05 mA	----	----
		患者辅助电流 B型、BF型应用部分	----	----
		正常状态：直流≤ 0.01 mA	----	----
		正常状态：交流≤ 0.1 mA	----	----
		单一故障状态:直流≤ 0.05 mA	----	----
		单一故障状态:交流≤ 0.5 mA	----	----
		患者辅助电流 CF型应用部分	----	----
		正常状态：直流≤0.01mA	----	----
		正常状态：交流≤ 0.01 mA	----	----
		单一故障状态：直流≤ 0.05 mA	----	----
		单一故障状态：交流≤0.05mA	----	----
正常工作温度下的电介质强度	20	试验时，设备承受规定的试验电压值1min，不应产生闪络或击穿		

河南省医疗器械检验所

检验检测报告

样品编号：急20200293

红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
正常工作温度下的电介质强度	20.1	对所有各类设备的通用要求：		
		A—a1（在带电部分和已保护接地的可触及金属部分之间）： V， Hz	----	----
		A—a2（在带电部分和未保护接地外壳部件之间）：DC500V	符合要求	合格
		A—b（在带电部分和以双重绝缘中的基本绝缘与带电部分隔离的导体部分之间）： V， Hz	----	----
		A—c（在外壳和以双重绝缘中的基本绝缘与带电部分隔离的导体部分之间）： V， Hz	----	----
		A—e（在非信号输入或信号输出部分的带电部分和未保护接地信号输入或信号输出部分之间）： V， Hz	----	----
		A—f（在网电源部分相反极性之间）： V， Hz	----	----
		A—g（在用绝缘材料作内衬的金属外壳和为试验目的用来与内衬内表面相接触的金属箔之间）： V，50Hz	----	----
		A—j（在电源软电线绝缘失效时会带电的未保护接地的可触及部飞和进线入口处套管内的、电线保护套内的、电线固定件内的或类似物件内的电源软电线上所缠绕的金属箔之间，或（和）插在软电线位置处其直径与软电线相同的金属杆之间）： V，50Hz	----	----
		A—k（依次在信号输入部分、信号输出部分和未保护接地的可触及部分之间）： V， Hz	----	----

河南省医疗器械检验所

检验检测报告

样品编号：急20200293

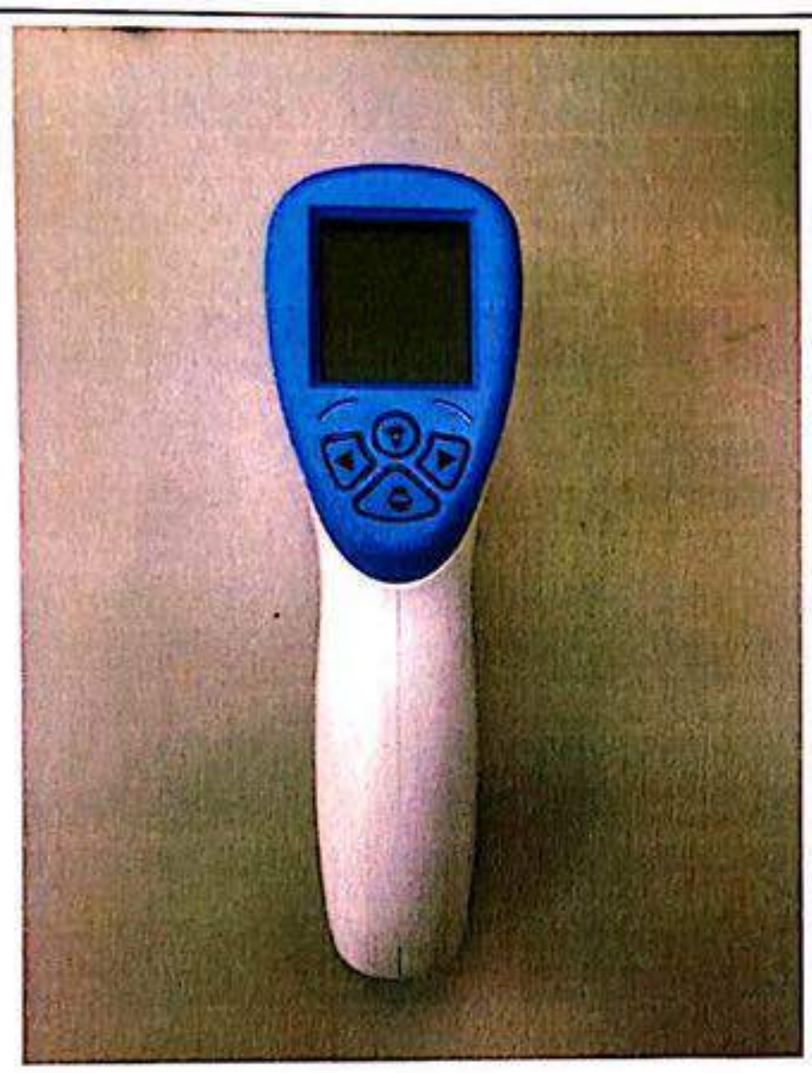
红外额温计				
检验项目	标准条款	标准要求	检验结果	单项结论
正常工作温度下的电介质强度	20.2	对有应用部分的设备的要求：		
		B—a（在应用部分（患者电路）和带电部分之间）：DC500V	符合要求	合格
		B—b（在应用部分各部件之间和（或）在应用部分与应用部分之间）： V， Hz	----	----
		B—c（在应用部分和仅用基本绝缘与带电部分隔离的未保护接地部件之间）： V， Hz	----	----
		B—d（在F型应用部分（患者电路）和包括信号输入部分及信号输出部分在内的外壳之间）：V， Hz	----	----
		B—e（在包括应用部分的任何部件接地的正常使用时，如F型应用部分上有电压使其与外壳之间的绝缘受到应力时，则在F型应用部分（患者电路）和外壳之间）： V， Hz	----	----
备注： 以下空白				

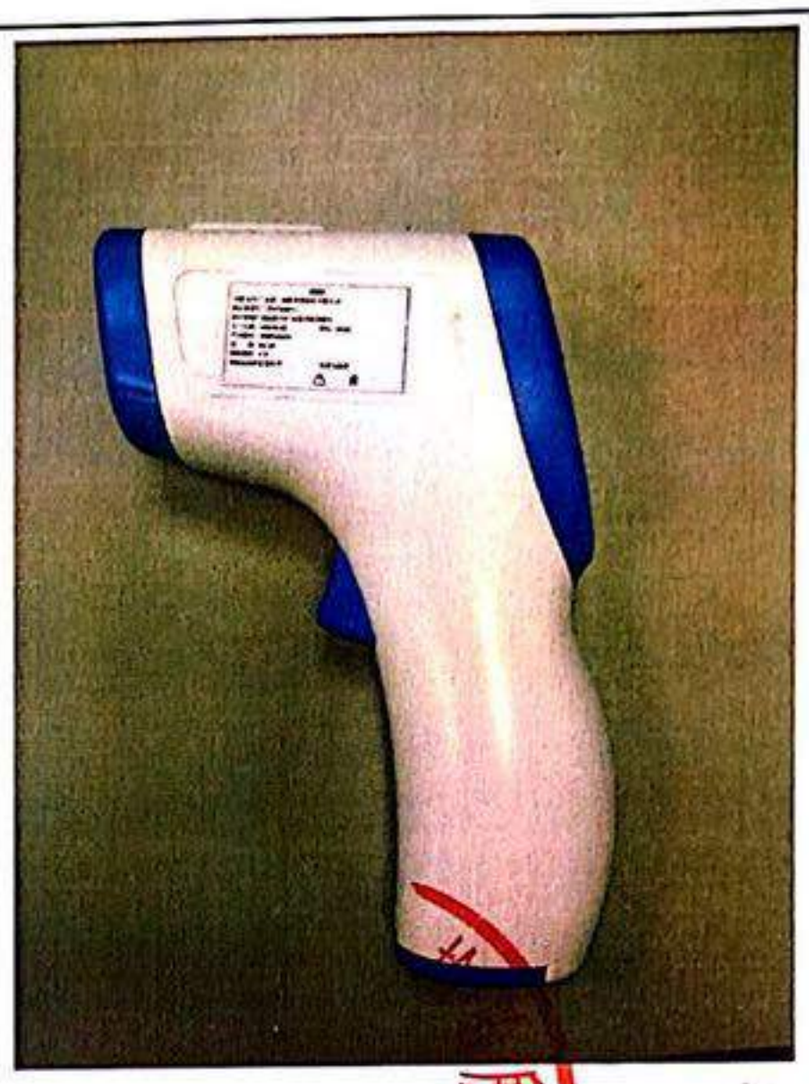
河南省医疗器械检验所

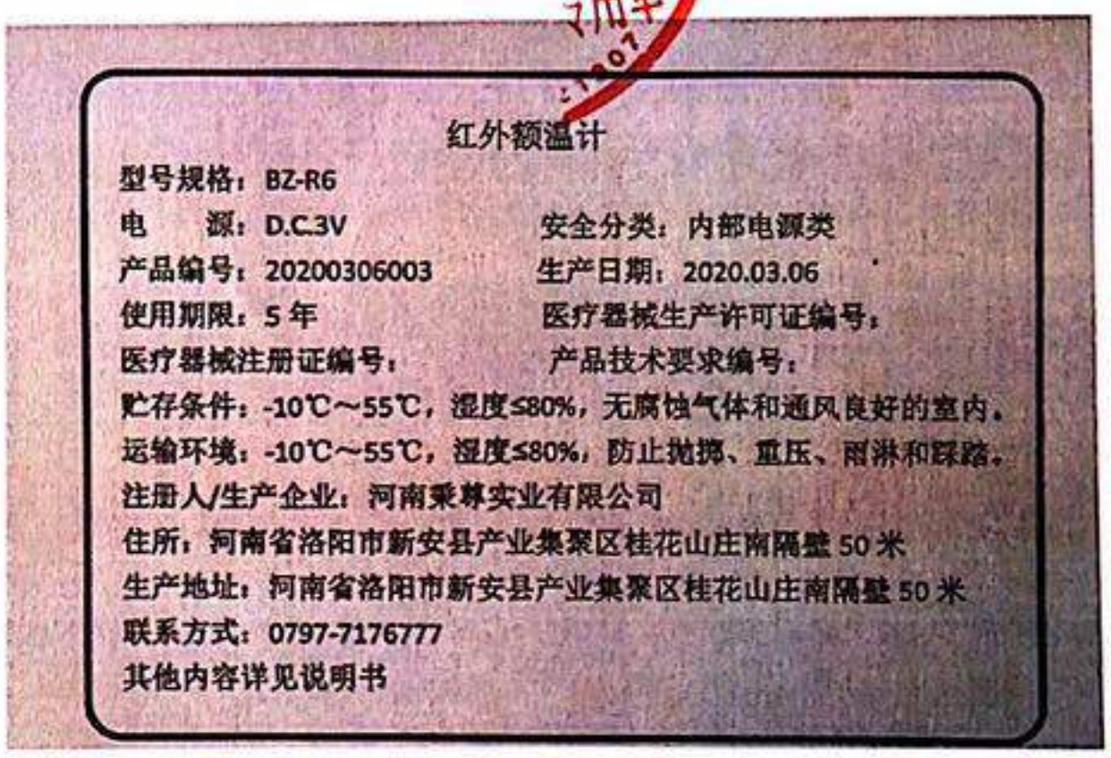
检验检测报告照片页

样品编号：急20200293

照片说明







样品描述

/

型号规格或其他说明

产品标示型号规格：BZ-R6

附页

医疗器械产品技术要求预评价意见表

样品编号：急20200293　　共 1 页 第 1 页

一、产品技术要求中性能指标的完整性与适用性；检验方法是否具有可操作性和可重复性，是否与检验要求相适应，此方面存在的问题：

无

二、依据现行强制性或推荐性国家标准、行业标准检验的，所用强制性国家标准、行业标准的完整性，所用标准与产品的适宜性，所用条款的适用性方面存在的问题：

无

三、如检验内容涉及引用中国药典的相关内容，其引用的完整性、适宜性和适用性，此方面存在的问题：

无

四、注册产品典型性判定及其他需要说明的问题：

仅对所检项目进行评价

五、综合评价意见：

■　经预评价，对产品技术要求无补充、完善意见。

□　经预评价，产品技术要求在以下方面需要进一步补充、完善：

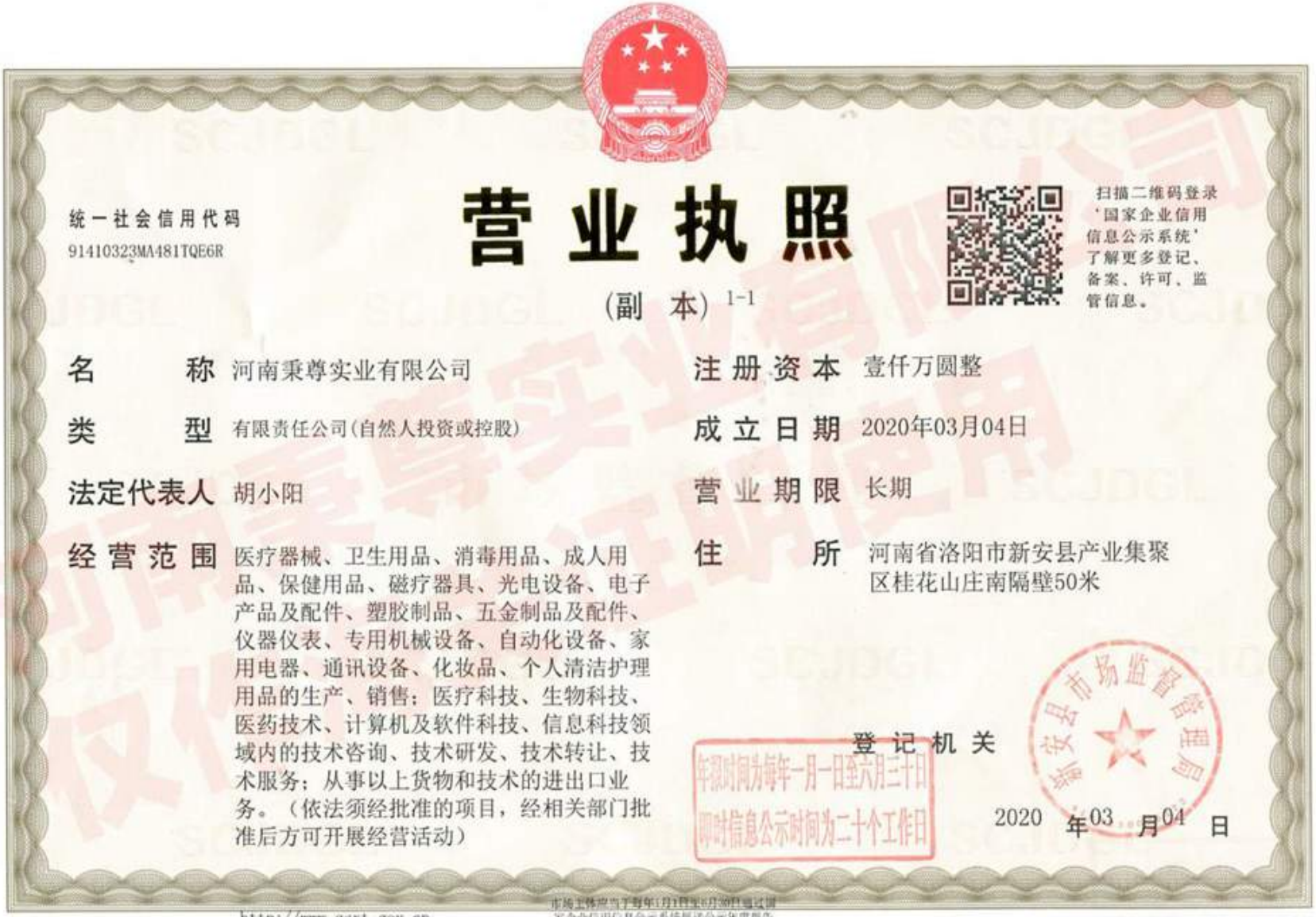
2020年03月19日

河南省医疗器械检验所 检验检测报告专用章 4101055421801

Bingzun Company Certificates

- **BUSINESS LICENSE**
- **MEDICAL DEVICE MANUFACTURE CERTIFICATE OF P.R.C**
- **REGISTRATION LICENSE OF MEDICAL INSTRUMENTS**
- **LICENSE CERTIFICATE OF CUSTOMS IMPORT AND EXPORT**

Bingzun Business license



统一社会信用代码
91410323MA481TQE6R

营业执照

(副 本) 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　河南秉尊实业有限公司

类　　型　有限责任公司(自然人投资或控股)

法定代表人　胡小阳

经营范围　医疗器械、卫生用品、消毒用品、成人用品、保健用品、磁疗器具、光电设备、电子产品及配件、塑胶制品、五金制品及配件、仪器仪表、专用机械设备、自动化设备、家用电器、通讯设备、化妆品、个人清洁护理用品的生产、销售；医疗科技、生物科技、医药技术、计算机及软件科技、信息科技领域内的技术咨询、技术研发、技术转让、技术服务；从事以上货物和技术的进出口业务。（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　壹仟万圆整

成立日期　2020年03月04日

营业期限　长期

住　　所　河南省洛阳市新安县产业集聚区桂花山庄南隔壁50米

登记机关

2020 年 03 月 04 日

年报时间为每年一月一日至六月三十日
即时信息公示时间为二十个工作日

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

Bingzun Medical Device Manufacture Certificate of P.R.C

医疗器械生产许可证

许可证编号：豫药监械生产许20200055号

企业名称：河南秉尊实业有限公司

生产地址：河南省洛阳市新安县产业集聚区桂花山庄南隔壁50米

新分类目录：07-03:生理参数分析测量设备※

法定代表人：胡小阳

生产范围：

企业负责人：胡小阳

住　　所：河南省洛阳市新安县产业集聚区桂花山庄南隔壁50米

发证部门：河南省药品监督管理局

有效期限：至　2021 年 04 月 02 日

发证日期：2020 年 04 月 03 日

国家食品药品监督管理总局制

REGISTRATION LICENSE OF MEDICAL INSTRUMENTS

中华人民共和国医疗器械注册证

注册证编号：豫械注准 20202071028

注册人名称	河南秉尊实业有限公司
注册人住所	河南省洛阳市新安县产业集聚区桂花山庄南隔壁 50 米
生产地址	河南省洛阳市新安县产业集聚区桂花山庄南隔壁 50 米
代理人名称	不适用
代理人住所	不适用
产品名称	红外额温计
型号、规格	BZ-R6
结构及组成	本产品由外壳、红外温度传感器、探头套、显示单元、供电电路、测量电路组成。
适用范围	采用红外感温方法测量并显示人体额头温度。
附　件	产品技术要求
其他内容	无
备　注	无

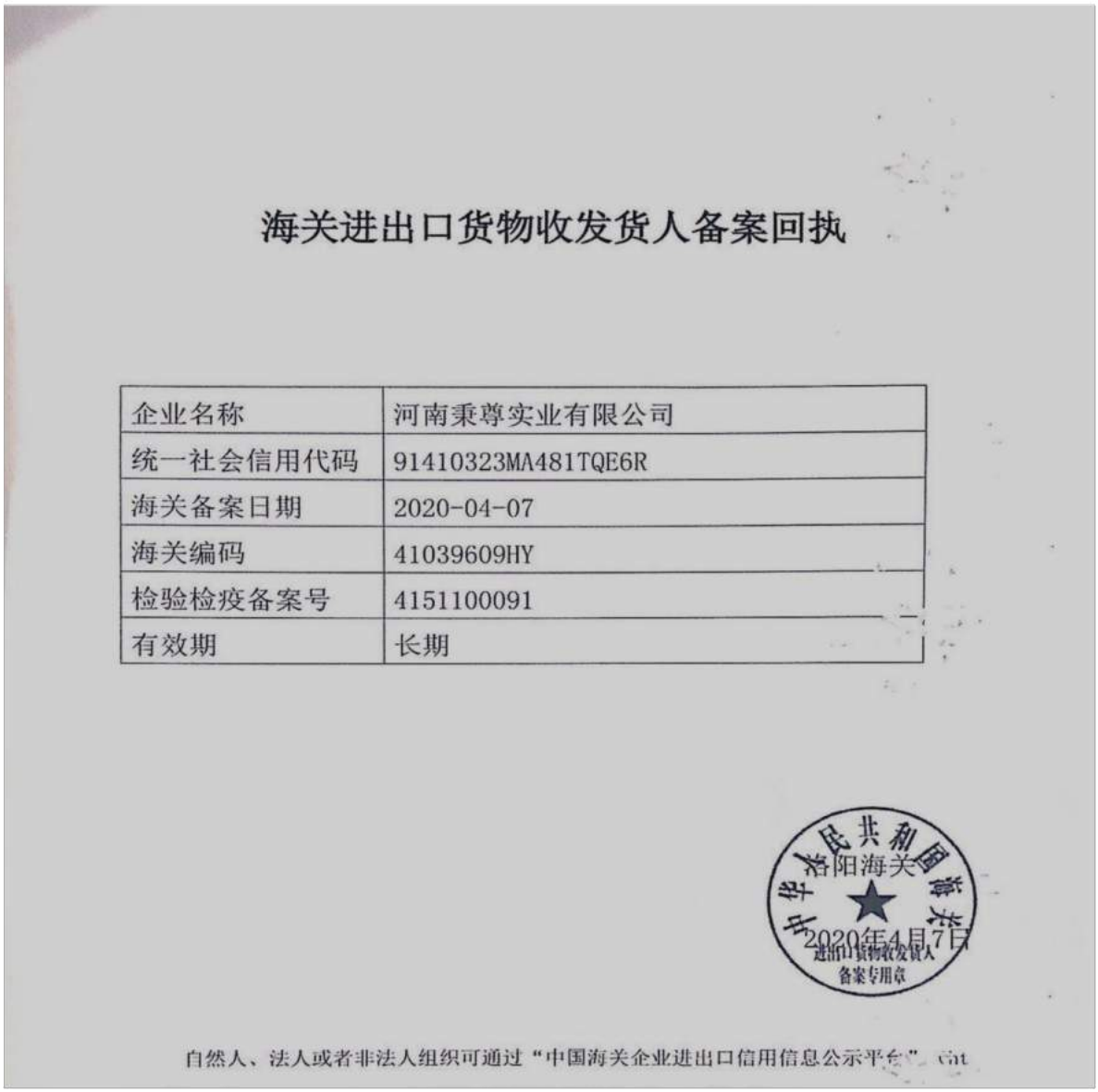
审批部门：河南省药品监督管理局

批准日期：二〇二〇年三月二十七日

有效期至：二〇二一年三月二十六日

（审批部门盖章）

LICENSE CERTIFICATE OF CUSTOMS IMPORT AND EXPORT



海关进出口货物收发货人备案回执

企业名称	河南秉尊实业有限公司
统一社会信用代码	91410323MA481TQE6R
海关备案日期	2020-04-07
海关编码	41039609HY
检验检疫备案号	4151100091
有效期	长期

中华人民共和国海关 洛阳海关

2020年4月7日

进出口货物收发货人 备案专用章

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”查

Bingzun Production Line

Thank You For Watching