
items: 109# Catalogue for IR forehead thermometer



Carton size : 47*35*29cm

40pcs/ctn

GW : 6.8 kgs/ctn

Infrared Forehead thermometer

- 1、 Product description
- 2、 Business license
- 3、 Manufacture license
- 4、 Resgistration certificate :201920700220
- 5、 Technical file :201920700220
- 6、 CE certificate
- 7、 ISO 13485 Certificate ISO13485
- 8、 Test report



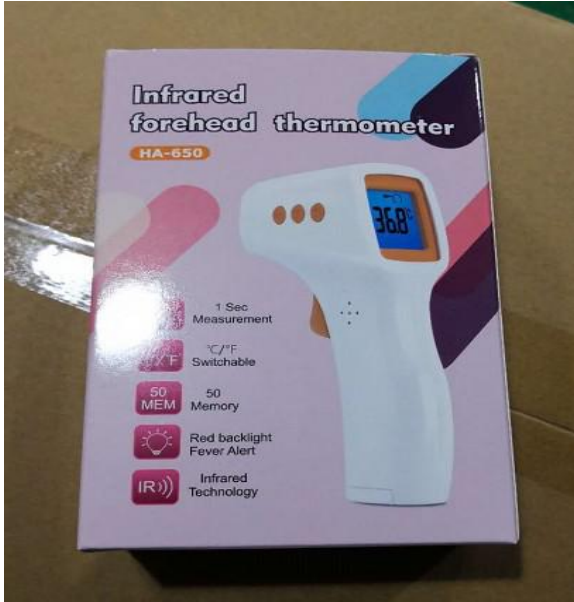
Non-contact Body Infrared Thermometer is specially designed to take the body temperature of a person.

- 1)One second can get the temperature from hand or forehead
- 2)Import Super chip

Regardless of the room temperature this little gadget is designed to accurately pick up on body heat! It does so in a hands-free, no-contact way.

The best deal Now, 3-7days you will be get it by DHL, EMS express.
Contact with us Get it,

Package for HA-650



EC Certificate Full Quality Assurance System: Certificate CN20/42012

The management system of

Xiamen Ants-Bro Technology Co., Ltd.

4F, 5th Building, Technology Business Establishing Center,
No.289 Wengjiao Road, Haicang District,
Xiamen City, Fujian Province, 361026, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

- Infrared forehead thermometer
- Digital clinical thermometer
- Automated non-invasive Sphygmomanometer

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 January 2020 until 25 March 2023 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 26 March 2015 and first certified by SGS Belgium NV since 16 January 2020

Certification is based on reports numbered CN/XMN 6428MD

Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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ISO13485质量体系证书

SGS

Certificate CN15/30421

The management system of

Xiamen Ants-Bro Technology Co., Ltd.

4F 5th Building, Technology Business Establishing Center,
No.289 Wengjiao Road, Haicang District,
Xiamen City, Fujian Province, 361026, P.R. China

has been assessed and certified as meeting the requirements of



ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Design and Manufacture of Digital clinical thermometer
and Automated non-invasive Sphygmomanometer
and Infrared forehead thermometer**

This certificate is valid from 30 October 2018 until 25 March 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 08 August 2020

Issue 3. Certified since 26 March 2015

Authorised by



0005

SGS United Kingdom Ltd
Rosemore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

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IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.....:	GZME180800078801
Date of issue.....:	2019-01-21
Total number of pages.....:	116
Testing Laboratory.....:	SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch
Address.....:	198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China
Applicant's name.....:	Xiamen Ants Bro Technology Co., Ltd.
Address.....:	4th, 5th Building, Technology business establishing center, No. 289 Wengjiao Road, Haicang District, Xiamen City, Fujian Province, China
Test specification:	
Standard.....:	IEC 60601- 1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	SGS-CSTC
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_1K
Test Report Form Originator.....:	UL(US)
Master TRF.....:	2015-11
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<p>General disclaimer:</p> <p>The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.</p>	



Test item description	Non-Contact Infrared Forehead Thermometer	
Trade Mark	---	
Manufacturer	Same as applicant	
Model/Type reference	HA-610, HA-620, HA-630, HA-640, HA-650	
Ratings	Internally powered: DC 3V (2xAAA batteries)	
Testing procedure and testing location:		
<input checked="" type="checkbox"/> Testing Laboratory:	SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch	
Testing location/ address	198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China	
<input type="checkbox"/> Associated CB Testing Laboratory:		
Testing location/ address		
Tested by (name, function, signature)	Gary Guo, George Gu / Project engineer <i>George Gu</i>	
Approved by (name, function, signature) ..	Aaron Cen / Reviewer <i>Aaron Cen</i>	
<input type="checkbox"/> Testing procedure: CTF Stage 1:		
Testing location/ address		
Tested by (name, function, signature)		
Approved by (name, function, signature) ..		
<input type="checkbox"/> Testing procedure: CTF Stage 2:		
Testing location/ address		
Tested by (name, function, signature)		
Witnessed by (name, function, signature) ..		
Approved by (name, function, signature) ..		
<input type="checkbox"/> Testing procedure: CTF Stage 3:		
<input type="checkbox"/> Testing procedure: CTF Stage 4:		
Testing location/ address		
Tested by (name, function, signature)		
Witnessed by (name, function, signature) ..		
Approved by (name, function, signature) ..		
Supervised by (name, function, signature) :		



List of Attachments (including a total number of pages in each attachment):	
<p>Attachment 1: Photo Documentation (from page 111 to page 115)</p> <p>Attachment 2: Circuit Diagram (page 116)</p>	
Summary of testing	
<p>Tests performed (name of test and test clause):</p> <p>Tests according to the following standards were carried out:</p> <p>IEC 60601-1:2005 + A1:2012 EN 60601-1:2006 + A1:2013</p> <p>The submitted samples fulfilled the requirements of specified standards except the following sub-clauses were not evaluated:</p> <p>Clause 12.2 and 15.1 Usability Clause 11.7 Biocompatibility Clause 14 PEMS</p> <p>HA-610 was subjected wo full tests.</p>	<p>Testing location:</p> <p>198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China</p>
Summary of compliance with National Differences	
<p>List of countries addressed:</p> <p>None</p>	

Test Report issued under the responsibility of:

SGS

TEST REPORT IEC 60601-1-11 MEDICAL ELECTRICAL EQUIPMENT – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	
Report Number.....	GZME180800078802
Date of issue	2019-01-18
Total number of pages	26
Name of Testing Laboratory preparing the Report	SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch
Applicant's name	Xiamen Ants Bro Technology Co., Ltd.
Address.....	4th, 5th Building, Technology business establishing center, No. 289 Wengjiao Road, Haicang District, Xiamen City, Fujian Province, China
Test specification:	
Standard	IEC 60601-1-11:2015 (Second Edition) for use in conjunction with IEC 60601-1:2012 (Third Edition) + A1:2012
Test procedure	SGS-CSTC
Non-standard test method	N/A
Test Report Form No.	IEC60601_1_11C
Test Report Form(s) Originator....	UL(US)
Master TRF	2015-03
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Test item description..... :	Infrared Forehead Thermometer	
Trade Mark..... :	---	
Manufacturer..... :	Same as applicant	
Model/Type reference..... :	HA-610, HA-620, HA-630, HA-640, HA-650	
Ratings..... :	Internally powered: DC 3V (2xAAA batteries)	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
<input checked="" type="checkbox"/> Testing Laboratory:	SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch	
Testing location/ address..... :	198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China	
<input type="checkbox"/> Associated CB Testing Laboratory:		
Testing location/ address..... :		
Tested by (name, function, signature)..... :	Gary Guo, George Gu <i>George Gu</i> Project engineer <i>Gary</i>	
Approved by (name, function, signature).... :	Aaron Cen / Reviewer <i>Aaron Cen</i>	
<input type="checkbox"/> Testing procedure: CTF Stage 1:		
Testing location/ address..... :		
Tested by (name, function, signature)..... :		
Approved by (name, function, signature).... :		
<input type="checkbox"/> Testing procedure: CTF Stage 2:		
Testing location/ address..... :		
Tested by (name + signature)..... :		
Witnessed by (name, function, signature) .. :		
Approved by (name, function, signature).... :		
<input type="checkbox"/> Testing procedure: CTF Stage 3		
<input type="checkbox"/> Testing procedure: CTF Stage 4		
Testing location/ address..... :		
Tested by (name, function, signature)..... :		
Witnessed by (name, function, signature) .. :		
Approved by (name, function, signature).... :		
Supervised by (name, function, signature) :		

List of Attachments (including a total number of pages in each attachment): None	
Summary of testing:	
Tests performed (name of test and test clause): Tests according to the following standards were carried out: IEC 60601-1-11:2015 EN 60601-1-11:2015 The submitted sample fulfilled the requirements of specified standards except the following clauses were not evaluated in this report: Clause 7.1, 8.1 and 9 Usability Clause 12 Electromagnetic compatibility requirement	Testing location: 198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China
Summary of compliance with National Differences: List of countries addressed None	
Copy of marking plate: See IEC 60601-1 Test Report No. GZME180800078801	

Test Report issued under the responsibility of:

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TEST REPORT ISO 80601-2-56 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	
Report Number.....	GZME180800078803
Date of issue	2019-01-18
Total number of pages	19
Applicant's name	Xiamen Arts Bro Technology Co., Ltd.
Address.....	4th, 5th Building, Technology business establishing center, No. 289 Wengjiao Road, Haicang District, Xiamen City, Fujian Province, China
Test specification:	
Standard	ISO 80601-2-56:2017 for use in conjunction with 60601-1:2005, COR1:2006, COR2:2007, AMD 1:2012
Test procedure.....	SGS-CSTC
Non-standard test method.....	N/A
Test Report Form No.	ISO80601_2_56B
Test Report Form(s) Originator	SGS CEBEC
Master TRF	Dated 2018-04-27
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Test item description.....	Infrared Forehead Thermometer
Trade Mark.....	—
Manufacturer	Same as applicant
Model/Type reference.....	HA-610, HA-620, HA-630, HA-640, HA-650
Ratings.....	Internally powered: DC 3V (2xAAA batteries)



Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):	
<input checked="" type="checkbox"/> Testing Laboratory:	SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou branch
Testing location/ address	198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China
Tested by (name, function, signature)	Gary Guo, George Gu Project engineer
Approved by (name, function, signature) ...:	Aaron Cen / Reviewer
<hr/>	
<input type="checkbox"/> Testing procedure: CTF Stage 1:	
Testing location/ address	
Tested by (name, function, signature)	
Approved by (name, function, signature) ...:	
<hr/>	
<input type="checkbox"/> Testing procedure: CTF Stage 2:	
Testing location/ address	
Tested by (name + signature)	
Witnessed by (name, function, signature) ..:	
Approved by (name, function, signature) ...:	
<hr/>	
<input type="checkbox"/> Testing procedure: CTF Stage 3	
<input type="checkbox"/> Testing procedure: CTF Stage 4:	
Testing location/ address	
Tested by (name, function, signature)	
Witnessed by (name, function, signature) ..:	
Approved by (name, function, signature) ...:	
Supervised by (name, function, signature) :	

<p>List of Attachments (including a total number of pages in each attachment): None</p>	
<p>Summary of testing:</p>	
<p>Tests performed (name of test and test clause): Tests according to the following standards were carried out: ISO 80601-2-56:2017 EN ISO 80601-2-56:2017 The submitted samples fulfilled the requirements of specified standards except the following clauses were not evaluated in this test report. Clause 201.11.7 Biocompatibility. Clause 201.7.9.2.101, 201.12.2.101 and 206 Usability. Clause 201.102 Clinical accuracy validation. Clause 202 Electromagnetic compatibility HA-610 was subjected wo full tests.</p>	<p>Testing location: 198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China</p>
<p>Summary of compliance with National Differences List of countries addressed: None.</p>	