## Simzo<sup>®</sup>



Mini Hot Medical Devices Baby Adult Forehead
Digital Infrared Thermometer
03/01/2020

## **Product Description**

### Overview

### **Quick Details**

Type:	Non-Contact Forehead Thermometer	Brand Name:	SIMZO or OEM
Place of Origin:	Guangdong, China	Model Number:	HW-F7
Instrument assification:	Class II	Warranty:	1 year
After-sale Service:	Free spare parts	Display:	LCD
Power supply:	2*AAA Batteries	Accuracy:	+/-0.2C°/0.4F°
Range:	34.0C°-43.0C°	Certificate:	CE ISO FDA
Packing:	Colour Box	Measurement mode:	Forehead type
Feature:	Three-color backlit	Sample:	Availble

### Supply Ability

Supply Ability: 100000 Piece/Pieces per Month

### Packaging & Delivery

Packaging Details

1pc/color box; 60pcs/CTN (470\*340\*315mm)

- color box X 1(163\*88\*47mm)

- Infrared Thermometer X 1

- User Manual X 1

- AAA battery X 2

Port:Shenzhen

Picture Example :



### Lead Time :

Quantity(Pieces)	1-10000	>10000
Est. Time(days)	20	To be negotiated

### Product Description

Device name	Non-Contact Forehead Thermometer
Model	HW-F7
Measurement mode	Object / Body
Power supply	D.C.3V, 2 AAA batteries
Measuring range	For forehead temperature: 34.0-43.0C°(93.2F°-109.4F°) For object surface temperature: 0-93C°(32F°-199.4F°)
Measuring accuracy	For forehead temperature:
(At laboratory conditions)	±0.2C°/0.4F° during 34.0C°-42.0C°;
	±0.3C°/0.5F° during 42.1C°-43.0C°.
Clinical repeatability	Within ±0.3C°/0.5F°
Resolution of display	0.1C°/0.1F°
Operation condition	15°C~40°C(59.0 F°~104 F°),Relative Humidity<95%
Storage condition	-25°C~55°C(13F°~131F°),Relative Humidity<95%
Size	136mm*76.5mm*38mm
Weight	About 75g
High body temperature hint	≥37.5C°(199.5F°) (Can be set)
Grade of waterproof	IP22
Electric shock	Internally powered ME equipment
Applied part	Type BF applied part, including the whole unit
Mode of operation	Continuous operation
Product life	5 years
Standard	EN60601-1,EN 12470-5 ,ASTM E 1965-98

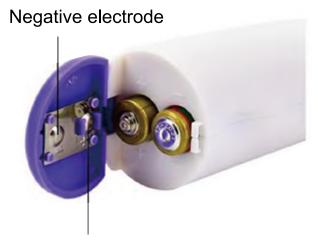
## PRODUCT DESCRIPTION

Streamline design, beautiful and practical feel.





Accurate measurement



Positive electrode

Powered by 2\*AAA Batteries

## Three-color backlight for easy reading







When the temperature value is higher than 37.4 °C, the color of backlight turns Orange with "bi,bi,bi"heard,and it is easy to know if the baby has a fever or not.

## PRODUCT APPLICATION

The product is suitable for all ages.Lt can dlso be used to measure object surface temperature.



Take temperature for kids



Take temperature for the aged

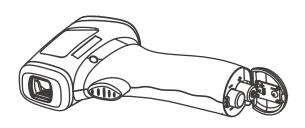


Take temperature for milk bottle

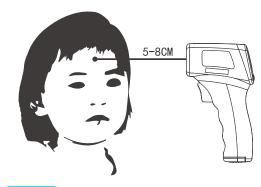


Take temperature for food

## **HOW TO USE?**





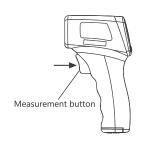


1

Open the battery storehouse, distinguishing the positive and Negative electrode then insert The batteries.

2

Align the thermometer probe at the Center of the forehead and keep it At distance of 5-8cm,be careful not To touch the forehead directly.











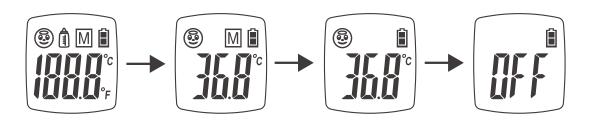


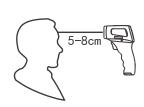
3

Select measurement mode, gently press the Measurement button to start measurement.

4

After successful measurement, the LCD screen displays the temperature value.





## **OUR CERTIFICATES**



December 6, 2018

Dongguan SIMZO Electronic Technology Co. Ltd. Mei Tan QA Manager No.81, Tianxin Street, Chongkong, Shijie Town Dongguan, Guangdong, China

Re: K173048

Trade/Device Name: Non-contact Forehead Thermometer, Model: HW-2/HW-2S/HW-3/HW-4/HW-

4S/HW-302/HW-303

Regulation Number: 21 CFR 880.2910

Regulation Name: Clinical Electronio Thermometer

Regulatory Class: Class II

Product Code: FLL Dated: October 22, 2018 Received: October 25, 2018

### Dear Mei Tan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <a href="https://www.accessdata.fda.gov/scripts/cdrh/efdocs/cfpmm/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/efdocs/cfpmm/pmn.cfm</a> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 K173048 - Mei Tan Page 2

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <a href="https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm">https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm</a>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<a href="https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/">https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/</a>) and CDRH Learn (<a href="http://www.fda.gov/Training/CDRHLearn">http://www.fda.gov/Training/CDRHLearn</a>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<a href="http://www.fda.gov/DICE">http://www.fda.gov/DICE</a>) for more information or contact DICE by email (<a href="DICE:meda.hhs.gov">DICE:meda.hhs.gov</a>) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K. Pamidlmukkala -S

for Tina Kiang, Ph.D.

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure



EC Certificate Production Quality Assurance System: Certificate CN19/41053

## Dongguan SIMZO Electronic Technology Co., Ltd.

No.81, Tianxin Street, Chongkou, Shijie Town, Dongguan City, Guangdong Province, 523290, P.R. China

has been assessed and certified as meeting the requirements of

### Directive 93/42/EEC

on medical devices, Annex V

For the following products

Infrared Thermometer used for measuring body temperature (Model:HW-1, HW-2, HW-2S,HW-3,HW-4,HW-4S, HW-302, HW-303, HW-F1, HW-F2, HW-F3, HW-F4,HW-F5,HW-F6,HW-F7); Portable (Ultrasonic) Nebulizer on Conscious Patients (NBM-1, NBM-2, NBM-3, NBM-3B,NBM-4,NBM-4B,NBM-5,NBM-5B, NBM-6, NBM-6B,NBM-7, NBM-7B, NBM-8, NBM-8B); Clinical Digital Thermometer (TH-801,TH-802,TH-803,TH-804,TH-805,TH-806,TH-807,TH-808,TH-809)

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III 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 December 2019 until 08 October 2022 and remains valid subject to satisfactory surveillance audits. Issue 1. Certified since 27 January 2015 and first certified by SGS Belgium NV since 16 December 2019

> > Certification is based on reports numbered CN/DGG/ 16426
> > Authorised by

### SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium 1 +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD9008 - Certificate CE1639 Annexi/\_EN rox 01

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Certificate CN14/31163

The management system of

# Dongguan SIMZO Electronic Technology Co., Ltd.

No. 81, Tianxin Street, Chongkou, Shijie Town, Dongguan City, Guangdong Province, 523290, P.R.China

has been assessed and certified as meeting the requirements of

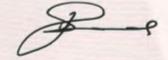
ISO 13485:2016 EN ISO 13485:2016

For the following activities

Manufacture of Infrared and Clinical Digital Thermometer used for measuring body temperature Manufacture of Nebulizer for medical use

This certificate is valid from 09 October 2017 until 08 October 2020 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 03 September 2020 Issue 3. Certified since 09 October 2014

Authorised by



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

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No 018043324

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This Certificate of Registration is hereby issued for the European Union trade mark identified below. The corresponding antries have been recorded in the Register of European Union trade marks.

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The Executive Director / Der Exekutivdirektor

Christian Archambeau

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### AMT DER EUROPÄISCHEN UNION FÜR GEISTIGES EIGENTUM

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732 Dongguan Simzo Electronic Technology Co., Ltd No.81, Tianxin Street, Chungkou, Shine Town 523290 Dongguan City, Guangdons

740. Nowicki, Sławomir Krzyszlof Podczachy 27 99-300 Kutno PL

270 EN DE

511 BG - 10

Аларати за масаж; Медицински вларати и инструменти: Дезинфекциращи [опушващи] апарати за медицински цели; Аларати за физически упражнения за медицински цели; Термометри за медицински цели; Аларати за измерване на кръвно налягане; Вапоризвтори за медицински цели; Ултравиолетови лампи за медицински цели; Тротези за коса; Бебешки шишета; Слухови апарати за тежкочуващи хора [слухов апарат].

ES - 10

Aparatos de masaje; Aparatos e instrumentos médicos; Aparatos de fumigación para uso médico; Aparatos de ejercicio físico para uso médico; Termómetros para uso médico; Esfigmomanómetros; Nebulizadores para uso médico; Lámparas de rayos ultravioleta para uso médico; Prófesis capitares; Biberones; Ayudas de audición para sordos [audifonos].

ES - 10

Masážní přístroje: Lékařské přístroje a nástroje; Fumigační přístroje pro lékařské účely; Přístroje na lělesná cvičení pro lékařské účely; Teplomäry pro lékařské účely; Přístroje na měření krevního tlaku; Nebulizátory pro lékařské účely; Lampy s-utrafialovým zářením pro tékařské účely, Vlasové prolézy; Dětské táhve; Pomůcky pro nedoslýchavé (akustické pomůcky).

DA - 18

Massageapparater, Medicinske apparater og instrumenter; Røgfrembringelsesapparater til medicinsk brug; Apparater til fysisk fræning til medicinske formål; Termometre til medicinsk brug; Blodtryksmålere; Inhalationsspray; Lamper til ultraviolet bestråling til medicinske formål; Kapillærtransplantater, Sutteflasker; Hørehjælpemidler til døve [akustiske hjælpemidler].

DE - 16

Massagegeráte; Medizinische Apparate und Instrumente; Räucherapparate für medizinische Zwecke; Medizinische Geräte für Körperübungen und Krankengymnastik; Thermometer für medizinische Zwecke; Blutdruckmessgeräte; Zerstäuber für medizinische Zwecke; Ultraviolettlampen für medizinische Zwecke; Haarprothesen; Saugflaschen; Hörgeräte für Schwerhörige (akustische Hilfsmittel).

ET - 10

Massaažiaparaadid; Meditsiiniseadmed ja -riistad; Meditsiinilised sultsutusaparaadid; Meditsiinilised võimlemisseadmed; Meditsiinilised termomeetrid; Arteriaalvererõhumõõturid, sfügmomanomeetrid; Aurustid (Meditsiinilised); Meditsiinilised ultraviolettlambid; Tehisjuuksed; Lutipudelid; Kuuldeaparaadid kurtidele (akustilised abivahendid).

EL - 10

Συσκευές μασος· Ιατρικά (Συσκευές και όργανα -)· Καπνού εκπομπή (συσκευές στμοθεραπείας) ιατρικής χρήσης· Ιατρικές συσκευές για σωματική άσκηση· Θερμόμετρα ιατρικά-Πιεσόμετρα· Εξατμιστήρες για ιατρική χρήση· Λαμπτήρες υπεριωδών ακτίνων για ιατρική χρήση· Προσθετικά μαλλιών· Υποδοχείς για θηλαστρα· Βοηθήματα ακοής για κωφούς.

EN - 10

Massage apparatus; Medical apparatus and instruments; Fumigation apparatus for medical purposes; Physical exercise apparatus, for medical purposes; Thermometers for medical purposes; Sphygmomanometers; Nebulizers for medical use; Ultraviolet ray lamps for medical purposes; Hair prostheses; Bables' bottles; Hearing aids for the deaf.

FR - 10

Appareils de massage; Appareils et Instruments médicaux; Appareils pour fumigations à usage médical; Appareils médicaux pour exercices corporels; Thermomètres à usage médical; Sphygmotarisomètres; Nébuliseurs à usage médical; Lampes à rayons ultraviolets à usage médical; Prothèses capillaires; Biberons; Appareils auditifs pour malentendants (corrections acoustiques).

II - 10

Apparecchi per il massaggio; Apparecchi e strumenti medici; Apparecchi per fumigazioni per uso medico; Apparecchi per esercizi fisici per scopi medici; Termometri per uso medico; Apparecchi per la misurazione della pressione arteriosa; Nebulizzatori per uso medico; Lampade a raggi ultravioletti per uso medico; Protesi capillari; Poppatoi; Apparecchi acustici per non udenti (protesi acustiche).

V - 18

Masāžas aparāli; Medicīniskā aparatūra un instrumenti; Furnigācijas ierīces medicīniskiem nolūkiem; Flzisko vingrinājumu ierīces medicīniskiem nolūkiem; Medicīniskie termometri; Asinsspiediena mērierīces; Inhalatori (iztvaicētāji) medicīniskiem nolūkiem; Ultravioletā starojuma lampas medicīniskiem nolūkiem; Matu protēzes; Zīdaiņu pudelīles; Dzirdes aparāti nedzirdīgajiem (akustiskie palīglīdzekļi).

LT - 10

Masažavimo aperatai; Medicinos aparatai ir instrumentai; Smilkymo prietaisai (medicinos reikmėms); Fizinių pratimų aparatai (medicinos reikmėms); Medicininiai termometrai; Sfigmotenzimetrai; Nebulizatoriai medicinos reikmėms; Ultravioletinės tempos (medicinos reikmėms); Dirbtiniai plaukai; Žindymo buteliukai; Klausos aparatai kurtiesiems (akustinės priemonės).

HR - 10

Uređaji za masažu; Medicinski uređaji i instrumenti; Uređaji za dimljenje za medicinske potrebe; Uređaji za vježba za medicinske potrebe; Toplomjeri za medicinske potrebe; Sfigmomanometri; Nebulizatori za medicinske primjene; Ultraljubičaste lampe za medicinsku namjenu: Kapilarne proteze; Spremnici dječjih bočica; Slušna pomagala za gluhe [akustlčna pomagala].

No 018043324

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HU - 18

Masszázsberendezések Gyógyászati heszülékek esehezök; Fertőtlenítő készülékek gyógyászati használatra; Testmozgásra szolgáló gyógyászati eszközök, készülékek; Hőmérők gyógyászati célokra; Vérnyornásmérő készülékek; Porlasztó készülékek gyógyászati használatra; UV lámpák gyógyászati célokra; Hajprotézisek; Cumisűvegtartók; Hallókészülékek nagyothaltók részére [akusztikus segédeszközők].

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#### MT - 18

Apparat ghall-massaģģi; Apparat u strumenti medici; Apparat ta' fumigazzjoni ģhal skopijiet medici; Apparat ghall-eżercizzju fiziku, ghal skopijiet medici; Termometri ghal skopijiet medici; Sfigmomanometri; Nebulizzaturi ghal užu mediku; Lampi taraģģi ultravjola ghal skopijiet medici; Protesi tax-xaghar; Recipjienti bhala filexken ghat-tmigh tat-trabi; Taghmir ghall-ghajnuna tas-smigh ghal min hu trux [ghajnuna akustika].

### NL - 10

Massageapparaten; Medische apparaten en instrumenten; Berokingsapparaten voor medisch gebruik; Medische apparatuur voor lichaamsoefeningen; Thermometers voor medisch gebruik; Bloeddrukmeetapparaten; Vernevelaars voor medisch gebruik; Ultravioletlampen voor medisch gebruik; Haarprolheses; Zuigflessen; Hoorapparaten voor doven [akoestische hulpmiddelen].

#### PL - 10

Urządzenia do masażu; Urządzenia i instrumenty medyczne; Urządzenia do fumigacji do celów medycznych; Urządzenia do świczeń fizycznych do celów medycznych; Termometry do celów medycznych; Aparaty do pomiaru ciśnienia tętniczego krwi; Nebulizatory do celów medycznych; Lampy ultrafioletowe do celów medycznych; Włosy (Sztuczne -); Pojemniki na butelki do karmienia; Aparaty słuchowe dla osób niesłyszących [aparaty akustyczne].

### PT - 10

Aparelhos de massagem; Aparelhos e instrumentos médicos; Aparelhos de fumigação, para uso médico; Aparelhos de exercício fisico para fins médicos; Termômetros para uso médico; Esfigmo-tensiómetros (medidores de tensão arterial); Nebulizadores para uso médico; Lámpadas ultravioletas de uso médico; Próteses capitares; Biberons [biberões]; Aparelhos acústicos para pessoas com deficiências auditivas.

### RO - 10

Aparate de masaj; Aparate și instrumente medicale; Aparate de fumigație pentru uz medical; Aparate pentru exerciții fizice de uz medical; Termometre de uz medical; Sfigmomanometre; Nebulizatoare de uz medical; Reze ultraviolete (lâmpi cu pentru uz medical); Proteze capitare; Recipiente pentru biberoane; Aparate auditive pentru persoane cu deficiențe de auz [proteze auditive].

### SK - 16

Masážne prístroje; Lekárske pristroje a nástroje; Inhalačné prístroje na lekárske použitie; Telocvičné pristroje na liečebně použitie; Lekárske teplomery; Krvně tlakomery; Rozprašovače na lekárske použitie; UV-lampy na lekárske použitie; Vlasově protězy; Detské flaše; Načúvacie pristroje pre nepočujúcich [akustické pomôcky].

### SL - 16

Masažne naprave; Medicinski aparati in instrumenti; Aparati za razkuževanje za medicinsko uporabo; Aparati za telesno vadbo za medicinske namene; Termometri za medicinske namene; Aparati za merjenje krvnega pritiska; Nebulizatorji za medicinsko uporabo; Ultravijolične svetilke za medicinske namene; Lasni vstavki; Posodice za stekleničke za hranjenje; Slušni pripomočki za gluhe [akustični pripomočki].

### FI - 10

Hierontalaitteet; Lääketieteelliset laitteet ja välineet; Kaasun tai höyryn sisäänhengityslaitteet lääkinnalliseen käyttöön; Kuntolluvälineet lääketieteellisiin tarkoituksiin; Kuumemittarit lääketieteellisiin tarkoituksiin; Verenpainemittarit; Sumuttimet lääkinnälliseen käyttöön; Ultraviolettisädelamput lääketieteelliseen käyttöön; Hiussiirteet; Tuttipullot; Kuulovammaisten kuulolaitteet [akustiset apuvalineet].

#### SV - 10

Massageapparater; Medicinska apparater och instrument; Apparater för inandning av gas eller ånga för medicinska ändamåt; Kroppsträningsapparater för medicinska ändamåt; Termometrar för medicinska ändamål; Blodtrycksmätare; Inhalationssprayer för medicinskt bruk; Ultravioletta strållampor för medicinska ändamål; Hårimplantat; Nappflaskor; Hörselhjälpmedel för döva [akustiska hjälpmedel].

3/3

### **OUR COMPANY**

## Dongguan SIMZO Electronic Technology Co.,Ltd

Dongguan SIMZO Electronic Technology Co.,Ltd, a professional manufacturer of medical infrared thermometer and nebulizer for home use and hospital use. We have ear thermometer, forehead thermometer, oral digital thermometer, portable ultrasonic nebulizer and compressor nebulizer.

SIMZO integrate research and development, manufacturing, marketing, distribution and sales of medical devices. It's most highlighted that SIMZO is backed by a top team of designers and engineers with more than 10 years of experience in the field of medical electronics. Meanwhile, SIMZO is dedicated to quality control and cost performance. These advantages make SIMZO a distinctive and trusted brand both for OEM projects and customization service.

To cater to universal customers, international quality requirements such as CE, FDA, MDD standards, as well as quality system ISO13485 have been met and attained. Over years, SIMZO already established long-term and strategic cooperation with CHICCO, AND, MOTHERCARE, BOOTS, CITIZEN, Auchan etc.

We will continue, as ever, to develop and innovate to meet the market demand. Bring the quality goods and good service to people across the world.





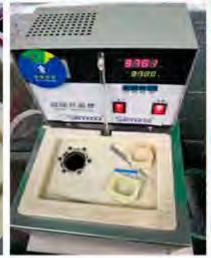














## **OUR CUSTOMERS**



## Q&A

- Obes your company own sales qualifications?
- Sour company has three certificates and is qualified for sales.







Ooes your Forehead Digital Infrared Thermometer own the export certification?

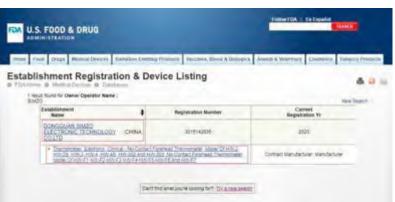
Our Forehead Digital Infrared Thermometer has dual FDA and CE certifications and can be exported worldwide (except South Korea). The certifications are as follows:



**FDA Operational Guidelines** 

Enter URL: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm Follow the below picture:





What is your company's payment method, what currency is accepted for payment, and what is the delivery way?

At present, our company only accepts cash transactions. If the demand is less than 3,000, full payment is required to be booked, and a deposit of 50% or more will be paid in advance. The final payment will be paid before shipment. It supports USD and RMB transactions, and can be FOB Hong Kong and FCA Hongkong.

### Company accounts are as follows:

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? Is it in stock and when will the goods be delivered to?

Solution Currently the stock is too limited. Pls make the reservation and arrange the payment, then our company arrange the production accordingly. The exact delivery time will be supplied according to the order quantity.

Is there a product picture?

Product pictures are as follows:

Color box size 163\*88\*47mm

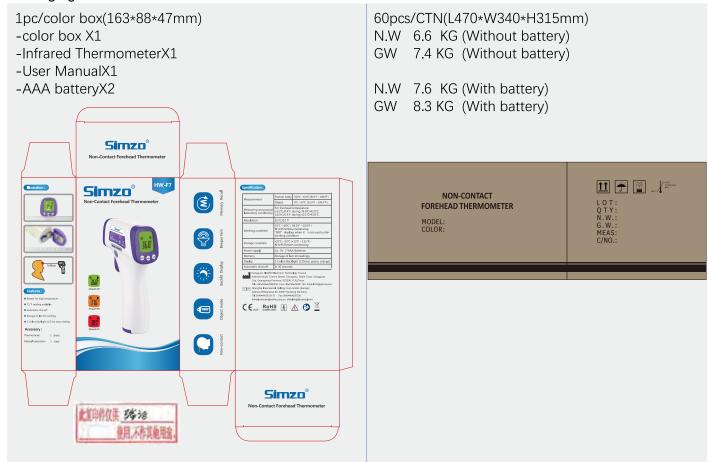




Can you provide product specifications, product models, packaging specifications?

Product model:Simzo HW-F7 English version

### Packaging Details



Open your Forehead Digital Infrared Thermometer have a quality guarantee and can perform after-sales service?

Product warranty is in accordance with the national warranty policy only within China.