ALIEN
since 2010

RAPID INDUCTION
ACCURATE MEASUREMENT

·Highly sensitive infrared probe·

·Noncontact measurement·

·1 second can be measured·

Medical Infrared Thermometer

AET-R1B1

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BLACK

WHITE

LED Digital Display

The black display box focuses the reading, the screen no longer changes color, only bright font. reading clear, and easy to get the temperature value.

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1 second measurement

High sensitive probe, the temperaturecan be measured in 1 second, after a measurement without other operations, you can enter the next measurement it is suitable for multi-person measurement or multi-time measurement.

Authoritative Certification of CE/FDA/CFDA

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U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

2/5/2018

Reanny Wang, Medical Device Consultant
Shenzhen Reanny Medical Devices Management Consulting Co, Lt
Room 2012 of Gebu commercial building, Hongxing, Songgang
Baoan District
Shenzhen, Guangdong 518000
CHINA

Dear Reanny Wang:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K180207
Received: 1/24/2018
Applicant: Alicn Medical (Shenzhen), Inc
Device: Non-contact Infrared Thermometer

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

ZERTIFIKAT ◆ CERTIFICATE ◆ CEPTИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 12 78453 014

Manufacturer: Alicn Medical Shenzhen, Inc
4/F, B Building
Shenfubao Modern Optical Factory, Kengzi Street
Pingshan District
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Renault-Petersen Limited
5 Bankside
Harborough Business Park
Witney
OX29 8LJ
UNITED KINGDOM

Product Category(ies): Clinical Infrared Thermometer,
Electronic Thermometer and Blood Pressure Monitor

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: GZ17052D1

Valid from: 2018-06-04
Valid until: 2022-05-07

Date, 2018-06-04

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

ALICN
since 2010

Ergonomic Design
Comfortable to Hold

Following ergonomic design rules,
the body is solid and stable,handiness,
comfortable grip, firm grasp

ALIEN
since 2010

Features

- a key measure
- memory storage
- replaceable battery
- a second display
- c/f switch
- forehead measurement
- hot tip
- LED display
- automatic shutdown
- intelligent accurate

Technical parameters

Measuring range：32.0℃~42.2℃

Accuracy：±0.2℃（35.0℃~42.0℃）

±0.3℃（32.0℃~34.9℃及42.1℃~42.2℃）

Resolution：0.1℃

Memory：32

Power supply ：2*AAA(DC 3V)

Dimension：144mm*101mm*26mm

Weight：88g(exclude battery)

Auto power-off：60s

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since 2010

PACKING SIZE

Qty./CTN(pcs)	42
gift box(mm)	120*175*50
carton box (mm)	380*370*375
CBM(m^3)	0.053
G.W (KG)	6.6

PACKAGE DISPLAY

ALICN
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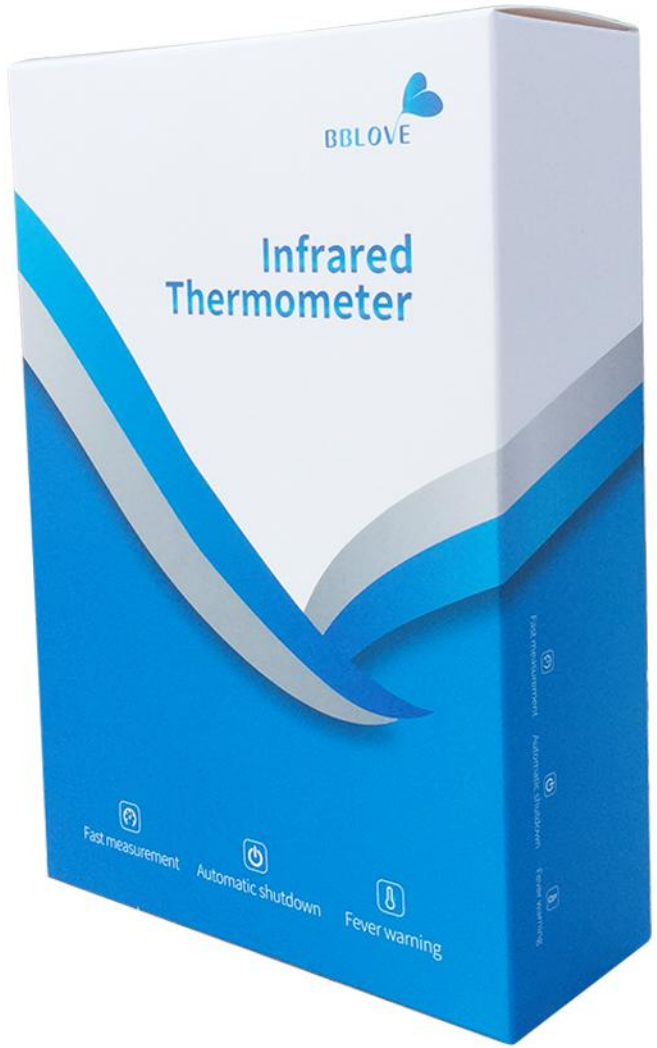

ALICN
since 2010

Alicn medical shenzhen Inc.
www.alicn-med.com

·END·