



AET-R161



Infrared Thermometer

[Overview]

This Infrared Thermometer, type AET-R161, is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of three months and above of people by detecting infrared heat from the center of the forehead.

[Features]



Fast measurement

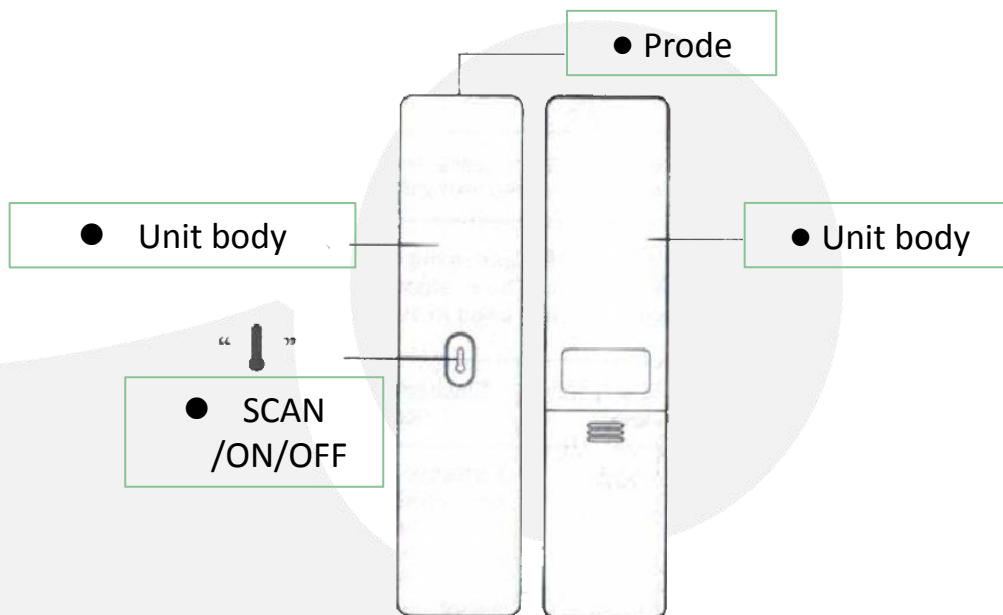


Automatic shutdown



Fever warning

[Unit Description]





Infrared Thermometer

[General Specifications]

Parameter	Specifications
Measurement Mode	Forehead mode
Measurement Units	Celsius(°C)and Fahrenheit(°F)
Operating Conditions	16°C-35°C(60.8°F to 95 °F) with a relative humidity of 15%-80%
Storage Conditions	-20°C-+55°C(-4°F to 131 °F) with a relative humidity of 15%-93%
Measurement distance	15mm to 50mm from the measuring point
Forehead temperature measurement range and accuracy	Measurement range: 32.0°C-42.2°C (89.6°F-108°F) Measurement accuracy: ±0.2°C (35.0°C-42.0°C)/ ±0.4°F(95.0°F-107.6°F)
Memories recall	32 measurements recall
Dimensions	150mmx 37mmx 16.3mm
Weight	51 g without batteries
Battery	2XAA batteries (DC.3V)
Switch off	Automatically switches off after 1 minute

Establishment Registration & Device Listing

FDA Home Medical Devices Databases



1 result found for Establishment Registration or Business Trade Name : ALICN MEDICAL SHENZHEN, INC

New Search

Establishment Name	Registration Number	Current Registration Yr
ALICN MEDICAL SHENZHEN, INC CHINA	3009889471	2020
<ul style="list-style-type: none"> Laryngoscope, Rigid 		Manufacturer
<ul style="list-style-type: none"> Thermometer, Electronic, Clinical - Non-Contact Infrared Thermometer AET-R161, AET-R171, AET-R1B1, AET-R1D2 And AET-R1D1; Non-Contact Infrared Thermometer AET-R1B6; Non-Contact Infrared Thermometer AET-R701, AET-R711, AET-R721, AET-R731, AET-R1F1 		Contract Manufacturer; Manufacturer
<ul style="list-style-type: none"> System, Measurement, Blood-Pressure, Non-Invasive - Arm Blood Pressure Monitor, Models Of AES-U111, AES-U141, AES-U511, AES-U312, AES-U512, AES-U531; Arm Blood Pressure Monitor, Models Of AES-U112, AES-U122, AES-U151, AES-U522, AES-U311 And AES-U321; Arm Blood Pressure Monitor, Models Of AES-U121, AES-U331, AES-U341, AES-U351, AES-U361, AES-U521; Arm Blood Pressure Monitor, Models Of AES-U171, AES-U181, AES-U131; Arm Blood Pressure Monitor, Models Of AES-U631, AES-U632, AES-U532, AES-U132, AES-U612, AES-U611 		Contract Manufacturer; Manufacturer

Establishment Registration & Device Listing

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New Search		Back To Search Results
Proprietary Name:	Non-contact infrared thermometer AET-R161, AET-R171, AET-R1B1, AET-R1D2 and AET-R1D1; Non-contact infrared thermometer AET-R1B6	
Classification Name:	THERMOMETER, ELECTRONIC, CLINICAL	
Product Code:	FLL	
Device Class:	2	
Regulation Number:	880.2910	
Medical Specialty:	General Hospital	
Registered Establishment Name:	ALICN MEDICAL SHENZHEN, INC	
Registered Establishment Number:	3009889471	
Premarket Submission Number:	K180207	
Owner/Operator:	Alicn Medical Shenzhen, Inc	
Owner/Operator Number:	10045880	
Establishment Operations:	Contract Manufacturer; Manufacturer	

Page Last Updated: 03/09/2020

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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



Product Service

CERTIFICATE

No. Q5 17 12 78453 013

Holder of Certificate: **Alicn Medical Shenzhen, Inc**

4/F, B Building
Shenfubao Modern Optical Factory, Kengzi Street
Pingshan District
518122 Shenzhen City
PEOPLE'S REPUBLIC OF CHINA



Certification Mark:



Scope of Certificate: Design and Development, Production and Sales of Clinical Electrical Thermometer, Clinical Infrared Thermometer, Blood Pressure Monitor and Video Laryngoscope

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1705201

Valid from: 2018-06-04
Valid until: 2021-02-07

Date, 2018-06-04

S. Preiß
Stefan Preiß



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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

CERTIFICATE

No. Q5 17 12 78453 013

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Alicn Medical Shenzhen, Inc
4/F, B Building, Shenfubao Modern Optical Factory, Kengzi
Street, Pingshan District, 518122 Shenzhen City, PEOPLE'S
REPUBLIC OF CHINA

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