

Lot nr.128. Termometru digital cu infrarosu Cod 260620, AET-R1B1, Alichn Medical

<i>Specificarea tehnică deplină solicitată, Standarde de referință</i>	<i>Specificarea tehnică deplină oferită, Standarde de referință</i>
Termometru digital cu infrarosu Cod 260620 Parametrul Specificația Descriere Termometru electronic pentru măsurarea temperaturii corpului uman, camerei si alte Afisaj alfanumeric LED / LCD Tip pacient nou-născut, pediatric, adult Regim de măsurare temperatura urechii (timpanic) temperatura fruntii (temporala) Diapazon de măsurare 34.0 - 43.0 °C Rezoluția de măsurare 0.1 °C Eroarea $\leq \pm 0.2$ °C Timp de măsurare ≤ 5 s Control on/off, deconectare automată Alarmer/indicatori Vizuală alerta febră temperatura finală baterie descărcată pornire/oprire Acustică temperatura finală Alimentare Baterie inclusa	Termometru digital cu infrarosu Cod 260620 Parametrul Specificația Descriere Termometru electronic pentru măsurarea temperaturii corpului uman, camerei si alte Afisaj alfanumeric LED / LCD Tip pacient nou-născut, pediatric, adult Regim de măsurare temperatura temperatura fruntii (temporala) Diapazon de măsurare 32.0 - 42.2 °C Rezoluția de măsurare 0.1 °C Eroarea $\leq \pm 0.2$ °C Timp de măsurare ≤ 5 s Control on/off, deconectare automată Alarmer/indicatori Vizuală alerta febră temperatura finală baterie descărcată pornire/oprire Acustică temperatura finală Alimentare Baterie inclusa



Product Service

Certificate

No. Q5 078453 0013 Rev. 01

Holder of Certificate: **Alicn Medical Shenzhen, Inc**
Room 410, Building A, 3rd Sub-park
Leibo Zhongcheng Life Science Park
No. 22 Jinxiu East Road, Jinsha Community, Kengzi Street
Pingshan District
518118 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



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

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 078453 0013 Rev. 01

Report No.: GZ2005201

Valid from: 2020-12-17

Valid until: 2023-12-16

Date, 2020-12-17

Christoph Dicks
Head of Certification/Notified Body

Certificate

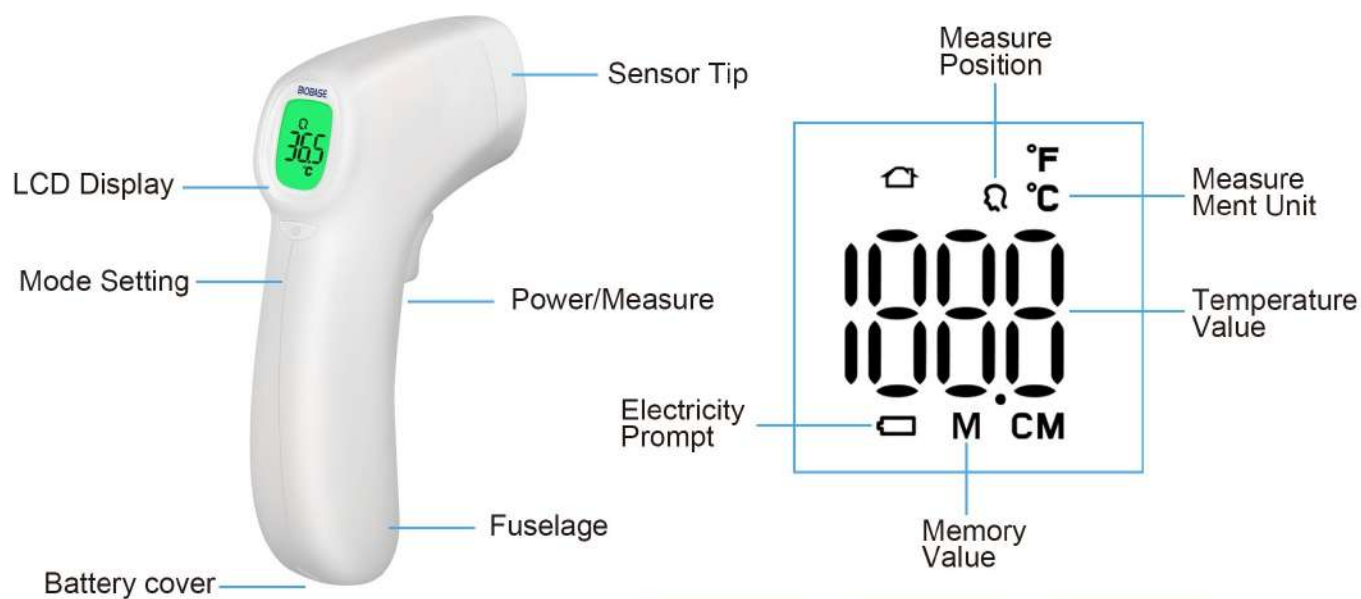
No. Q5 078453 0013 Rev. 01

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
Room 410, Building A, 3rd Sub-park, Leibo Zhongcheng Life
Science Park, No. 22 Jinxiu East Road, Jinsha Community, Kengzi
Street, Pingshan District, 518118 Shenzhen, Guangdong,
PEOPLE'S REPUBLIC OF CHINA

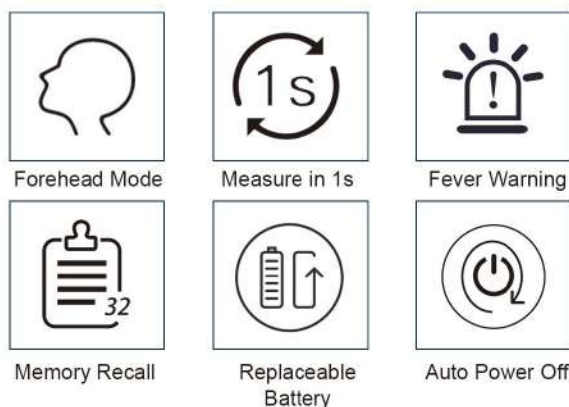
Design and Development, Production and Sales of Clinical
Electrical Thermometer, Clinical Infrared Thermometer and Blood
Pressure Monitor

Infrared Thermometer



Features

1. Non-touch measurement
2. High precision infrared sensor
3. Practical patent design
4. High definition display



Technical Parameters

Model	AET-R1B1
Product Size	37mm*78mm*144mm (L*W*H)
Product Weight	62g
Memory	32 groups
Operating Temp	5°C~40°C
Measuring Mode	Forehead Mode
Measurement Range	32.0°C~42.2°C
Accuracy	±0.2°C (35.0°C~42.0°C) ; ±0.3°C (32.0°C~34.9°C / 42.1°C~42.2°C)
Voltage Source	2*1.5 V Batteries: size AAA
Automatic Power Off	60s



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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 078453 0014 Rev. 02

Manufacturer:

Alicn Medical Shenzhen, Inc

Room 410, Building A, 3rd Sub-park
Leibo Zhongcheng Life Science Park
No. 22 Jinxiu East Road, Jinsha Community, Kengzi Street
Pingshan District
518118 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2_078453_0014_Rev_02

Report No.: GZ2005201

Valid from: 2020-12-17

Valid until: 2022-05-07

Date, 2020-12-17

Christoph Dicks
Head of Certification/Notified Body