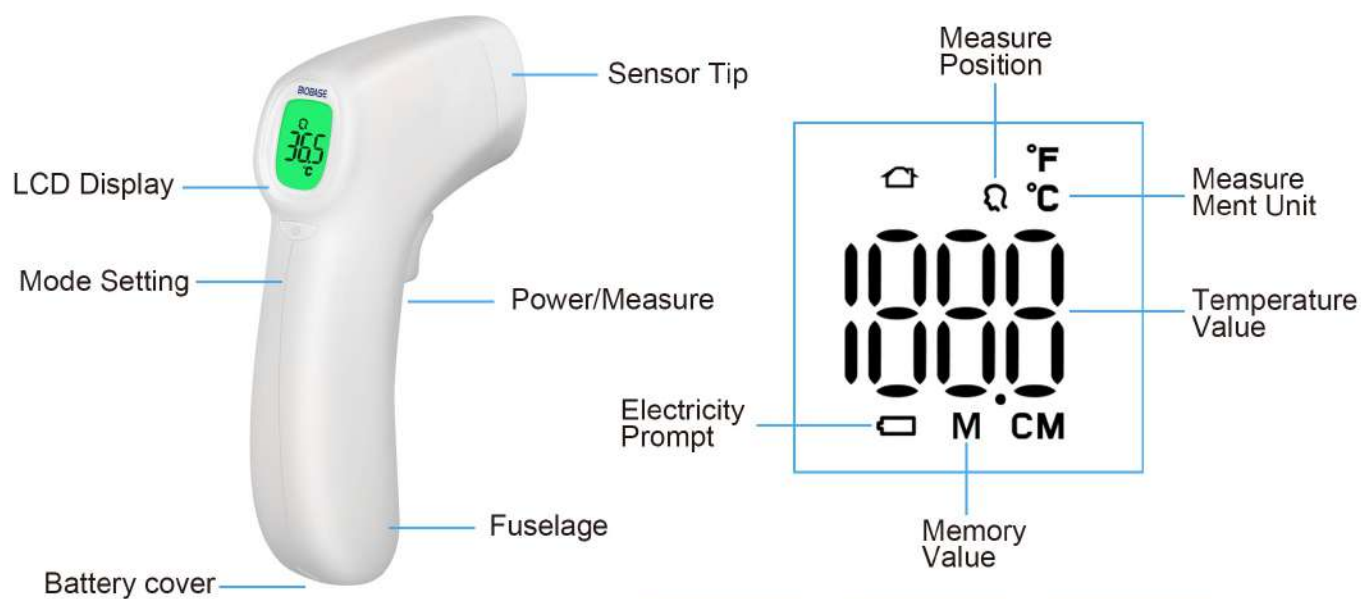


Lot nr.40 Termometru digital cu infrarosu Cod 260620, AET-R1B1, Alicn Medical Shenzen Inc, China

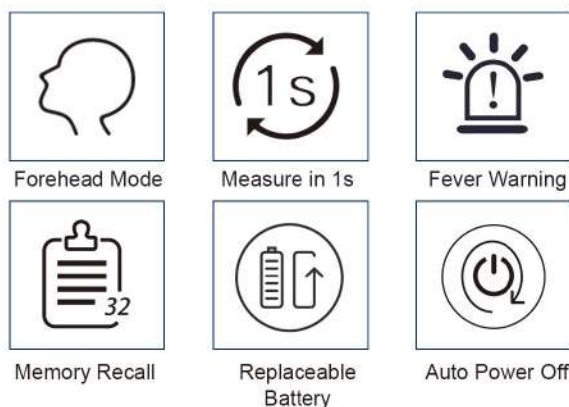
<i>Specificarea tehnică deplină solicitată, Standarde de referință</i>	<i>Specificarea tehnică deplină oferita, Standarde de referință</i>
Termometru digital cu infrarosu Cod 260620 Parametrul Specificația Descriere Termometru electronic pentru măsurarea temperaturii corpului uman, camerei si alte Afișaj alfanumeric LED / LCD Tip pacient nou -născut, pediatric, adul t 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 Alarmerindicatori 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 Afișaj alphanumeric LCD Tip pacient nou -născut, pediatric, adult Regim de măsurare 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 Alarmerindicatori Vizuală alerta febră temperatura finală baterie descărcată pornire/oprire Acustică temperatura finală Alimentare Baterie inclusa

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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



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. 01

Manufacturer:

Alicn Medical Shenzhen, Inc

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

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

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.:

GZ1805201

Valid from:

2019-07-15

Valid until:

2022-05-07

Date,

2019-07-15

Stefan Preiß
Head of Certification/Notified Body



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 relevant standard(s). See also notes overleaf.

Report No.: GZ1705201**Valid from:** 2018-06-04**Valid until:** 2021-02-07**Date,** 2018-06-04

Stefan Preiß



Page 1 of 2





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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