

Trouble shoot

Error indicators

The following symbols will appear on the display when measurement is abnormal

Symbol	Correction
	In Body Mode, Measured temperature is above Measuring range of 43°C/109.4 °F, it is shown on the LCD with red LED.
	In Body Mode, Measured temperature is below the Measuring range of 32°C/89.6 °F, it is shown on the LCD with red LED.
	In Object Mode, Measured temperature is above Measuring range 100.0°C/212.0 °F, or environmental temperature is above system Operating range 40°C/104.0 °F, it is shown on the LCD with red LED.
	In Object Mode, Measured temperature is below Measuring range 0.0°C/32.0 °F, or environmental temperature is below system operating range 5°C/41.0 °F, it is shown on the LCD with red LED.
	Low battery, replace all the worn batteries with new ones
ERR	Thermometer system fails or affected by electric magnetic field

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Specification

Description	Non-contact Infrared Forehead Thermometer
Display	LCD digital display
Measuring localization	Forehead and object surface
Measurement range	Body mode 32.0°C~43.0°C (89.6°F~109.4°F); Object mode 0.0~100.0°C (32.0°F~212.0°F);
Temperature unit	°C/°F
Display resolution	0.1°C/0.1°F
Accuracy	±0.2°C/±0.4°F (within 36.0°C~39.0°C/96.8°F~102.2°F)
Memory function	Last memory of measurement values
Power source	2 pcs AAA alkaline battery
Automatic power-off	In 30 seconds
Main unit weight	Approx. 95g (batteries not included)
Main unit size	95mm*45mm*155mm
Battery life	Could be used for 500 times for normal condition
Measurement time	1-2 sec
Operating environment	Body mode 10.0°C~40.0°C/50.0°F~104.0°F Object mode 5°C~40.0°C/41.0°F~104.0°F
Storage environment	Temperature: -20°C~+55°C/-4.0°F~+131.0°F Humidity: RH≤85% does not condense avoid crash, sunburn or rain during transportation

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Care and maintenance

Care for the main unit

- Keep the unit in the storage case when not in use.
- Clean the unit with a soft dry cloth. Do not use any abrasive or volatile cleaners.
- Never immerse the unit or any of its component in water.

Maintenance

Do not clean the unit with naphtha, thinner or gasoline etc.	Store the unit in a clean and dry location. Do not subject the unit to extreme hot or cold temperature, humidity and direct sunlight.
Remove the batteries if the unit will not be used in 3 months or longer.	Do not use the unit under the influence of electromagnetic interference (nearby cellphones, microwave etc.)

Note: We will not be responsible for any quality problem if you do not care and maintain the product as instructed.

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Warranty information

▲ The unit is guaranteed to be free of defects in workmanship and materials under normal use for a period of 1 Year from the date of purchase.

▲ For repair under this warranty. Our authorized service agent must be advised of the fault within the period of the warranty. This warranty only covers parts and labor service under normal operations. Any defect resulting from natural causes, eg. flood, hurricane etc., is not covered in this guarantee. This guarantee also does not cover damage incurred by use of the unit not in accordance with the instructions, accidental damage, or being tampered or serviced by unauthorized service agents.

▲ The following will be excluded from this warranty if the thermometer has been misused, abused, or neglect in following the manual's instructions on purpose and unauthorized repair or modifications.

▲ The device requires no calibration.

▲ The device is not repairable and contains no user serviceable parts.

ShenZhen Medek Bio-Medical Co., Ltd.
ADD: No. 101 Wenhao Industrial Park No. 13 Yuanxin Road
Tongle Community, Baolong Street, Longgang District.
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Made in China

Apr. 2020. ver. 1.1

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DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES



MANUFACTURER:

NAME: SHENZHEN MEDEK BIO-MEDICAL CO., LTD.

Add: No. 101 Wenhao Industrial Part No. 13 Yuanxin Road Tongle Community,
Baolong Street Longgang District 518100 Shenzhen People's Republic of China

MEDICAL DEVICE: NAME: *Infrared Thermometer*

MODEL : MDI907, MDI111

CLASSIFICATION - ANNEX IX: CLASS IIb, RULE10

CONFORMITY ASSESSMENT ROUTE: ANNEX II

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE
93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

No. G1.093979 0005 REV. 00



EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffeistrasse 80, 20537 Hamburg, Germany

START OF CE-MARKING:

PLACE, DATE OF DECLARATION:

SHENZHEN DATE: 05-09-2019

SIGNATURE

NAME: LIU XIANGMING

POSITION: GENERAL MANAGER



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

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 093979 0005 Rev. 00

Manufacturer:

ShenZhen Medek Bio-Medical Co., Ltd.

No.101 Wenhao Industrial Park
No.13 Yuanxin Road
Tongle Community, Baolong Street
Longgang District
518100 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

ShenZhen Medek Bio-Medical Co., Ltd.
No.101 Wenhao Industrial Park, No.13 Yuanxin Road, Tongle
Community, Baolong Street, Longgang District, 518100
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Infrared Thermometer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

GZ1821801

Valid from:

2018-08-09

Valid until:

2023-09-08

Date,

2018-08-09

Stefan Preiß



Certificate

No. Q5 093979 0006 Rev. 00

Holder of Certificate: **ShenZhen Medek Bio-Medical Co., Ltd.**

No.101 Wenhao Industrial Park
No.13 Yuanxin Road
Tongle Community, Baolong Street
Longgang District
518100 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

ShenZhen Medek Bio-Medical Co., Ltd.
No.101 Wenhao Industrial Park, No.13 Yuanxin Road, Tongle
Community, Baolong Street, Longgang District, 518100
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Infrared Thermometer and Blood Pressure Monitor**

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

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.: GZ1921801

Valid from: 2019-10-17

Valid until: 2022-09-08

Date, 2019-10-17

Stefan Preiß
Head of Certification/Notified Body