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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 101165 0003 Rev. 00

Manufacturer: **Kangfu Medical Equipment Factory**
No.380 Ningkang East Road
325600 Yueqing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Luxus Lebenswelt GmbH
Kochstr. 1, 47877 Willich, GERMANY

Product Category(ies): **Digital Thermometers, Infra-red Thermometers, Diigital Blood Pressure Monitors (Sphygmomanometers)**

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.

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Date, 2019-01-29

Stefan Preiß



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Facility(ies):

Kangfu Medical Equipment Factory
No.380 Ningkang East Road, 325600 Yueqing, Zhejiang,
PEOPLE'S REPUBLIC OF CHINA

DIGITAL THERMOMETER

KFT-01/KFT-02



- Model No.: KFT-01
- Display: LCD, 3.5digits, 19mm×7.5mm
- Temperature measurement: thermistor
- Apply for: Oral / Axillary / Rectal
- 60 seconds response
- Sound warning when peak temperature is reached
- Fever alarm
- Accuracy: $\pm 0.1^{\circ}\text{C}$ ($\pm 0.2^{\circ}\text{F}$)
- Resolution: 0.1°C (0.1°F)
- Measurement scope: $32^{\circ}\text{C}\sim 42.9^{\circ}\text{C}$ ($89.6^{\circ}\text{F}\sim 109.2^{\circ}\text{F}$)
Temperature $< 32^{\circ}\text{C}$ (89.6°F) display Lo $^{\circ}\text{C}$ (Lo $^{\circ}\text{F}$);
Temperature $> 42.9^{\circ}\text{C}$ (109.2°F) display Hi $^{\circ}\text{C}$ (Hi $^{\circ}\text{F}$);
- Waterproof level: IPX2
- Memory records: 1 set
- Low voltage indication
- Automatically turn-off function (8 min)

- Validity: 3 years (Batteries are not included and the product can be used after calibration by a qualified body)
- Power source and voltage: DC 1.5V, LR41 or AG3
- Battery life: about 1200 times or 1 year
- Dimension: 125mm×18mm×9.2mm
- Unit weight: Approx. 10g (Including battery)
- Work environment:
Temperature $5^{\circ}\text{C}\sim 40^{\circ}\text{C}$ ($41^{\circ}\text{F}\sim 104^{\circ}\text{F}$); Humidity: 15%RH~85%RH;
Atmospheric pressure: 70KPa~106KPa;
- Transport/Storage condition:
Temperature $-20^{\circ}\text{C}\sim 55^{\circ}\text{C}$ ($-4^{\circ}\text{F}\sim 131^{\circ}\text{F}$); Humidity: 10%RH~85%RH;
Atmospheric pressure: 70KPa~106KPa;

- Model No.: KFT-02
- Display: LCD, 3.5digits, 15.6mm×6mm
- Temperature measurement: thermistor
- Apply for: Oral / Axillary / Rectal
- 60 seconds response
- Sound warning when peak temperature is reached
- Fever alarm
- Accuracy: $\pm 0.1^{\circ}\text{C}$ ($\pm 0.2^{\circ}\text{F}$)
- Resolution: 0.1°C (0.1°F)
- Measurement scope: $32^{\circ}\text{C}\sim 42.9^{\circ}\text{C}$ ($89.6^{\circ}\text{F}\sim 109.2^{\circ}\text{F}$)
Temperature $< 32^{\circ}\text{C}$ (89.6°F) display Lo $^{\circ}\text{C}$ (Lo $^{\circ}\text{F}$);
Temperature $> 42.9^{\circ}\text{C}$ (109.2°F) display Hi $^{\circ}\text{C}$ (Hi $^{\circ}\text{F}$);
- Waterproof level: IPX7
- Memory records: 1 set
- Low voltage indication
- Automatically turn-off function (8 min)

- Validity: 3 years (Batteries are not included and the product can be used after calibration by a qualified body)
- Power source and voltage: DC 1.5V, LR41 or AG3
- Battery life: about 1200 times or 1 year
- Dimension: 119mm×15.6mm×9.3mm
- Unit weight: Approx. 7g (Including battery)
- Work environment:
Temperature $5^{\circ}\text{C}\sim 40^{\circ}\text{C}$ ($41^{\circ}\text{F}\sim 104^{\circ}\text{F}$); Humidity: 15%RH~85%RH;
Atmospheric pressure: 70KPa~106KPa;
- Transport/Storage condition:
Temperature $-20^{\circ}\text{C}\sim 55^{\circ}\text{C}$ ($-4^{\circ}\text{F}\sim 131^{\circ}\text{F}$); Humidity: 10%RH~85%RH;
Atmospheric pressure: 70KPa~106KPa;



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INFRA-RED THERMOMETER

KFT-22M



- Model No.: KFT-22M
- Display: LCD, 3.5digits, 34mm×21mm
- Backlight display: 3 colors;
≤37.4°C (99.3°F) display green;
37.5°C~37.9°C (99.5°F~100.2°F) display orange;
≥38.0°C (100.4°F) display red;
- Temperature measurement: infrared scan
- Measurement mode: ear temperature, forehead temperature, objects temperature, environment temperature
- 1 seconds fast response
- Fever alarm
- Accuracy:
ear temperature, forehead temperature
(35°C~42°C) ±0.2°C; (95°F~107.6°F) ±0.4°F;
(32°C~34.9°C) ±0.3°C; (89.6°F~94.8°F) ±0.5°F;
(42.1°C~42.9°C) ±0.3°C; (107.8°F~109.2°F) ±0.5°F;
objects temperature, environment temperature
(0°C~100°C) ±1.0°C; (32°F~212°F) ±1.8°F;
- Resolution: 0.1°C (0.1°F)

-Measurement scope:

ear temperature, forehead temperature: 32°C~42.9°C (89.6°F~109.2°F)
Temperature <32°C (89.6°F) display Lo°C (Lo°F);
Temperature >42.9°C (109.2°F) display Hi°C (Hi°F);
objects temperature, environment temperature: 0°C~100°C (32°F~212°F)

-Waterproof level: IPX2

-Memory records: 20 sets

-Low voltage indication

-Auto stand-by: not in use for 25 seconds will auto skip to time display

-Validity: 5 years (Batteries are not included and the product can be used after calibration by a qualified body)

-Power source and voltage: DC 3V (2pcs 1.5V AAA battery)

-Battery life: about 1200 times (Continuous measurement under 25°C / 77°F room temperature)

-Dimension: 145mm×37mm×35mm

-Unit weight: Approx. 53g (Not including battery)

-Work environment:

Temperature 15°C~35°C (59°F~95°F); Humidity: 15%RH~85%RH;
Atmospheric pressure: 70KPa~106KPa;

-Transport/Storage condition:

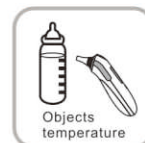
Temperature -25°C~55°C (-13°F~131°F); Humidity: 10%RH~90%RH;
Atmospheric pressure: 70KPa~106KPa;



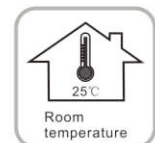
Ear temperature



Forehead temperature



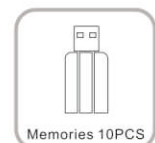
Objects temperature



Room temperature



Clock



Memories 10PCS

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