滚沟响



EC Certificate

Directive 93/42/EEC Annex V

仅限

Production Quality Assurance 有限公司 Medical Devices

Registration No.:

DD 60144980 0001

Report No.:

17063021 002

Manufacturer:

ShenZhen ZhengKang Technology

Co., Ltd.

2&3/F, Building A, No.3 FuXing Yi Lane

HeHua Community, PingHu Street

LongGang District

ShenZhen

518100 Guangdong

P.R. China

Products:

Blood Pressure Monitors

Expiry Date:

2020-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class Mg and class III devices covered by this certificate an EG type-examination certificate according to Appear III is required.

Effective Date:

2020-04-16

Date:

2020-04-16

Motified Body

Tivemeinland

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



Certificate

Quality Management System EN ISO 13485:2016

Registration No.:

SX 2182322-1

Organization:

ShenZhen ZhengKang Jechnogy Co., Ltd.

2&3/F, Building A, No 3 Filking Yi Lane, HeHua Congranit,

PingHu Street, Long District,

ShenZhen

518100 Guaring

P.R. Chica

Scope:

Manufacture and Distribution of Blood Pressure Monitors;

Design and Development, Manufacture and Distribution of Infrared

Thermometers, Nebulizers, Oximeters

TUVPhemand

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:

10919075-100

Effective date:

2022-03-24

Expiry date:

2022-12-26

Issue date:

2022-03-24

Dipl.-Ing. W. Hsu

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

TÜVRheinland



ARM BLOOD PRESSURE MONITOR

WRIST BLOOD PRESSURE MONITOR



Product introduction:

- Product size: 126mm x 105mm x 50mm;
- Double 99 groups memory function;
- Display: LCD digital display;
- Measurement: pulse scanning/oscillography;
- Measurement range: hypertension/hypotension:20mmHg-280mmHg;
- Pulse: (40-200) times/min;

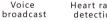
- Resolution: 1mmHg (0.1kpa);
- Accuracy: ±3mmHg (± 0.4kpa);
- Pulse: within \pm 3% of the reading;
- Power consumption: 0.01W;
- WHO blood pressure classification;











- Measurement method: oscillometric method;
- Measure arm circumference: 22-32cm;
- Measurement range: pulse rate 40-199 times/minute, blood pressure value 0-299mmHg;
- Measurement accuracy: blood pressure value ±3mmHg;
- Working environment: temperature +5- +40°C, humidity 15%-85%RH;
- LED high-definition color screen, clearly visible at night;

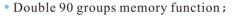


FYD1162

Product introduction:

- Product size: 77.5mm×68mm×30mm;
- Double 90 groups memory function;
- Display: Digital liquid crystal display;
- Voltage power detection, Low power consumption;
- Accuracy: ±3mmHg (±0.4kPa);
- Auto power off: Auto power off when no operation for 1 minute;
- Fashionable outward, Light and compact, Easy to carry, suitable for health care(medical field, familes and adult);
- WHO blood pressure classification;





- Average calculating for the latest 3 times measurement value;
- Year/month/date/time function;
- Accuracy: Pressure +/-3mmHg;
- Pulse: within ± 5% of the reading;
- Automatic power-off function;
- WHO blood pressure classification;
- LED high-definition color screen, clearly visible at night;







detection memory









FYD1164