

派合司部



## EC Certificate

Directive 93/42/EEC Annex V

Production Quality Assurance

Medical Devices

深圳市正康科技有限公司  
证件管理专用章  
仅限 使用  
可复印于外 编号

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 II and class III devices covered by this certificate an ISO type-examination certificate according to Annex II is required.

Effective Date: 2020-04-16

Date: 2020-04-16

Notified Body

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 Technology Co., Ltd.  
2&3/F, Building A, No.3 Shixing  
Yi Lane, HeHua Community,  
PingHu Street, LongGang District,  
ShenZhen  
518100 Guangdong  
P.R. China

Scope: Manufacture and Distribution of Blood Pressure Monitors;  
Design and Development, Manufacture and Distribution of Infrared  
Thermometers, Nebulizers, Oximeters

TÜV Rheinland

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

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## 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:  $\pm 3$ mmHg ( $\pm 0.4$ kpa);
- Pulse: within  $\pm 3\%$  of the reading;
- Power consumption: 0.01W;
- WHO blood pressure classification;



**FYD1161**



Voice broadcast



Heart rate detection



Double memory

- 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  $\pm 3$ mmHg;
- Working environment: temperature  $+5^{\circ}\text{C}$  -  $+40^{\circ}\text{C}$ , humidity 15%-85%RH;
- LED high-definition color screen, clearly visible at night;



**FYD1162**

## ARM BLOOD PRESSURE MONITOR



## 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 :  $\pm 3$ mmHg ( $\pm 0.4$ kPa) ;
- 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, families and adult) ;
- WHO blood pressure classification ;

- Double 90 groups memory function ;
- Average calculating for the latest 3 times measurement value;
- Year/month/date/time function;
- Accuracy :Pressure  $\pm 3$ mmHg;
- Pulse: within  $\pm 5\%$  of the reading;
- Automatic power-off function;
- WHO blood pressure classification;
- LED high-definition color screen,clearly visible at night;



**FYD1164**

## WRIST BLOOD PRESSURE MONITOR



**FYD1163**



Voice broadcast



Heart rate detection



Double memory