



# 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 078672 0014 Rev. 01**

**Manufacturer:** **Shenzhen Urion Technology Co., Ltd.**  
Floor 4-6th of Building D  
Jiale Science & Technology Industrial Zone  
No.3, ChuangWei Road  
Heshuikou Community, MaTian Street  
GuangMing New District  
518106 Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies): Digital Blood Pressure Monitors, Infrared Thermometer, Compressor Nebulizers**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10786720014Rev.01](http://www.tuvsud.com/ps-cert?q=cert:G10786720014Rev.01)

**Report No.:** GZ2117902

**Valid from:** 2021-04-12

**Valid until:** 2024-05-26

**Date,** 2021-04-12

Christoph Dicks  
Head of Certification/Notified Body

## 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;



**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- +40°C, humidity 15%-85%RH;
- LED high-definition color screen, clearly visible at night;



**FYD1162**

## ARM BLOOD PRESSURE MONITOR

- 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;

## WRIST 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 ;



**FYD1163**

- 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;

- Voice broadcast
- Heart rate detection
- Double memory



**FYD1164**