

### Department of Health

Therapeutic Goods Administration

## **Australian Register of Therapeutic Goods Certificate**

Issued to

### Frontida Health

for approval to supply

# Frontida Health - Blood Pressure Monitor U82RH - Automatic-inflation electronic sphygmomanometer, portable, arm/wrist

ARTG Identifier 387551

ARTG Start Date 27/04/2022

Product Category Medical Device Included Class IIa

**GMDN** 45617

GMDN Term Automatic-inflation electronic sphygmomanometer, portable, arm/wrist

Intended Purpose An automatic blood pressure monitor intended to measure the systolic

pressure, diastolic pressure and pulse rate through the upper arm. It is expected to be used at home, or a hospital and intended for anyone 12

ARTG Identifier: 387551

ARTG Start Date: 27/04/2022

years or older.

Manufacturer Details	Address	Certificate number(s)
Shenzhen Urion Technology Co Ltd	Floor 4-6th of Building D Jiale Science & Technology Industrial Zone No 3 ChangWei Road Heshuikou Community MaTian Street GuangMing New District , Shenzhen , 518106 China	DV-2022-MC-09130-1

### **ARTG Standard Conditions**

The above Medical Device Included Class IIa has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
  - Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### **Products Covered by This Entry**

1. Blood Pressure Monitor U82RH - Automatic-inflation electronic sphygmomanometer, portable, arm/wrist

#### **Product Specific Conditions**

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration PO Box 100, Woden ACT 2606 Australia Phone: 1800 020 653 Email: info@tga.gov.au