Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

WIWE Australia

for approval to supply

WIWE Australia - Single-channel electrocardiograph

ARTG Identifier	294151
ARTG Start date	20/09/2017
Product Category	Medical Device Included Class IIa
GMDN	11413
GMDN Term	Single-channel electrocardiograph
Intended Purpose	WIWE is simple to operate. The users turn on the device, connect it to a smartphone via Bluetooth, and gently place their two thumbs, or any two fingers, on the electrode sensors. WIWE will record a user's ECG for one minute while also capturing SpO2. The ECG can be observed in real time on the smartphone screen. Following the measurement, the device then provides immediate feedback on the data collected.It has the ability to estimate the state of the user's heart muscle cells through the Ventricular repolarization Heterogeneity (VH) parameter. WIWE also offers improved detection of atrial fibrillation through its evaluation of the user's P wave on the ECG.

Manufacturer Details	Address	Certificate number(s)
Sanatmetal Ortopediai es Traumatologiai Eszkozoket Gyarto Kft	Faiskola u. 5 , Eger, 3300 Hungary	DV-2017-MC-07043-1

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. Single-channel electrocardiograph

Product Specific Conditions

.