



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 337191 RNA Pharmaceuticals Pty Ltd - Oximeter, pulse

ARTG entry for Medical Device Included Class IIb
Sponsor RNA Pharmaceuticals Pty Ltd
Postal Address 17 Perugia Avenue, Greenvale, VIC, 3059
Australia
ARTG Start Date 28/05/2020
Product Category Medical Device Class IIb
Status Active
Approval Area Medical Devices

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.

Manufacturers

Name	Address
Shenzhen Yimi Life Technology Co Ltd	305 Building A Tengbo Industrial Park Changshangjiang Street Longbei Village Pingshan District, Shenzhen, 518118 China

Products

1 . Oximeter, pulse

Product Type	Single Device Product	Effective Date	28/05/2020
GMDN	17148 Oximeter, pulse		
Intended Purpose	Pulse Oximeter Portable, non-invasive device for spot-check of oxygen saturation of arterial hemoglobin (SPO2) and pulse rate of adult and pediatric user.		

Specific Conditions

No Specific Conditions included on Record

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