



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	347132	Silverline Medical Pty Ltd - Oximeter, pulse
ARTG entry for	Medical Device Included Class IIb	
Sponsor	Silverline Medical Pty Ltd	
Postal Address	14/265 Pennant Hill Road Thornleigh, SYDNEY NSW AUSTRALIA, NSW, 2120 Australia	
ARTG Start Date	3/11/2020	
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
Rossmax Innotek Corp	12F No 189 Kang Chein Road , Taipei, 11494 Taiwan

Products

1 . Oximeter, pulse			
Product Type		Effective Date	
Single Device Product		3/11/2020	
GMDN	17148 Oximeter, pulse		
Intended Purpose	A device for transcutaneous measurement of oxygen saturation in the blood using light detection to illuminate arterial tissue blood. The device also measures pulse rate and artery condition.		

Specific Conditions
No Specific Conditions included on Record

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