



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 346370 Zone Medical Pty Ltd - Infusion pump, general-purpose

ARTG entry for Medical Device Included Class IIb

Sponsor Zone Medical Pty Ltd

Postal Address PO Box 641, ORMEAU, QLD, 4208
Australia

ARTG Start Date 22/10/2020

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
Micrel Medical Devices SA	42 Konstantinoupoleos str Koropi Athens, Greece, 19441 Greece

Products

1 . Infusion pump, general-purpose

Product Type	Single Device Product	Effective Date	22/10/2020
GMDN	13215 Infusion pump, general-purpose		
Intended Purpose	A device that facilitates accurate and consistent administration of liquids into a patient by intravenous, intra-arterial, subcutaneous, intraperitoneal, in close proximity to nerves, into an intraoperative site, epidural space, or subarachnoid space infusion.		

Specific Conditions

No Specific Conditions included on Record

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