



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 312644 PX 210 Pty Ltd T/a New Medical - ivWatch - Intravenous access monitoring system, infiltration/extravasation

ARTG entry for Medical Device Included Class IIa
Sponsor PX 210 Pty Ltd T/a New Medical
Postal Address Unit 13 / 23 Breene Place, MORNINGSIDE, QLD, 4170
 Australia
ARTG Start Date 18/12/2018
Product category Medical Device Class IIa
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
ivWatch LLC	1100 Exploration Way Suite 209 Hampton, VA, 23666 United States Of America

Products

1. ivWatch - Intravenous access monitoring system, infiltration/extravasation

Product Type	Effective date
Medical device system	18/12/2018
GMDN	62252 Intravenous access monitoring system, infiltration/extravasation
Intended purpose	ivWatch is a monitoring device of non-vital physiological parameters. ivWatch monitors intravenous infusion sites and it can detect extravasation and infiltration alerting the caregiver to stop the infusion and resite the intravenous drip.

Specific Conditions

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