



**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	700 Tech Center Parkway Suite 300 Newport News, VA, 23606 United States Of America

**Products**

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

Product Type	Medical device system	Effective Date	18/12/2018
<b>GMDN</b>	62252 Intravenous access monitoring system, infiltration/extravasation		
<b>Intended Purpose</b>	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**

No Specific Conditions included on Record

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