



Medical Device Details

Sponsor: Clinical & Regulatory Services Limited
P O Box 766
Hastings
New Zealand

WAND Reference: 230420-WAND-711YDU

Sponsors Own Reference: ivWatch_62252_Class IIa

GMDN: Infiltration/extravasation monitoring system [62252]

Class: IIa

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.

Manufacturer: ivWatch LLC 700 Tech Center Parkway, Suite 300
Newport News
Virginia
United States

ARTG ID:

- ▣ > The device is supplied sterile.
 - > Sterilisation method: Ethylene oxide
- > The device is not intended to be invasive.
- > The device is intended for single use.
- > The device is an active device.
- > The device does not contain material or ingredients of microbial origin.
- > The device does not contain material or ingredients of recombinant origin.
- > The device does not contain material or ingredients manufactured or formulated using a genetically modified organism.
- > The device does not contain material or ingredients of human origin.
- > The device does not contain human blood or its components.
- ▣ > The device consists of: System
 - > The device does not contain material or ingredients of animal origin.
 - > The device is not medicated.
 - > The device is not formulated.
 - > The product does not contain a medicine that has consent for marketing in New Zealand.
 - > The product does not contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device.

Status: Active