

# Medical Device Details

Sponsor: S.D. Studio LP  
61B St Georges Bay Road  
Parnell  
Auckland  
New Zealand

WAND Reference: 180421-WAND-6Q6WWC

Sponsors Own Reference: FistulaLink\_v1

GMDN: Pump, [13192]

Class: Ila

Intended Purpose: Pump for reinfusion of enteric fistula or stoma nutrients

Manufacturer: SDS Push Ltd 61B St Georges Bay Road  
Parnell  
Auckland  
New Zealand

## ARTG ID:

- › The device is supplied unsterilised.
- › 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: Single product
- › 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