Medical Device Details

Sponsor:	Pharmaco (NZ) Ltd P O Box 4079 AUCKLAND NEW ZEALAND
WAND Reference:	100311-WAND-68JSQ6
Sponsors Own Reference:	InsuJet
GMDN:	Needleless medication/vaccine injector, mechanical [18069]
Class:	IIb
Intended Purpose:	The InsuJet is designed for subcutaneous administration of insulin, without the use of needles, by patients, healthcare professionals or non-professional carers. The device is meant to be for single person use only.
Manufacturer:	European Pharma Group BV Euro Offices Building 3e Beechavenue 127 1119 RB Schiphol-Rijk Schiphol-Rijk THE NETHERLANDS
ARTG ID:	180917

- The device is supplied unsterilised.
- The device is intended to be invasive.
- The device is not intended for single use.
- The device is not 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
    - Components:
        - Component: 10mL Vial Adaptor, Vial adaptor suitable for 10ml insulin vials
        - Component: 3mL Cartridge Adaptor, Vial adaptor suitable for 3ml insulin cartridges
        - Component: Cartridge Cap Removal Key, Key which helps to remove the cartridge cap on 3mL insulin cartridges
        - Component: Comfort Ring, Reduces the pressure of the Nozzle on the skin
        - Component: Nozzle & Piston, Nozzle to administer the insulin
- 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