



Medical Device Details

Sponsor: CARSL Consulting
P O Box 766
Hastings 4156
New Zealand

WAND Reference: 080925-WAND-7JT6P7

Sponsors Own Reference: RestorativeTherapies_RT300 FES cycle ergometer_Class IIa

GMDN: Bicycle ergometer [10383]

Class: IIa

Intended Purpose: The RT300 FES cycle ergometer is intended to be used for: 1. muscle re-education; 2. relaxation of muscle spasms; 3. prevention or retardation of disuse atrophy; 4. increasing local blood circulation; 5. maintaining or increasing range of motion.

Manufacturer: Restorative Therapies Inc 1434 Fleet Street
Baltimore
Maryland 21231
UNITED STATES OF AMERICA

ARTG ID: 152657

- › The device is supplied unsterilised.
- › The device is not intended to be invasive.
- › The device is not 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
 - ☐ Components:
 - › Model: ., RT300-SL RT300-SLSA RT300-LSA RT300-SLA RT300-SLP RT300-SLSA supine RT300-SLA supine RT300-LA supine
 - › 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