

### **Australian Government**

# **Department of Health**

Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

# Emergo Asia Pacific Pty Ltd T/a Emergo Australia

for approval to supply

Emergo Asia Pacific Pty Ltd T/a Emergo Australia- RT200 FES elliptical ergometer, RT300 FES cycle ergometer, RT600 FES stepper ergometer - Stimulator, evoked response, electrical

**ARTG** Identifier 176355 **ARTG Start date** 

Medical Device Included Class IIa **Product Category** 

**GMDN** 

**GMDN Term** Stimulator, evoked response, electrical

6/10/2010

**Intended Purpose** The RT200, RT300 and RT600 are intended for general rehabilitation

1. Relaxation of muscle spasms

2. Prevention or retardation of disuse atrophy

3. Increasing local blood circulation

4. Maintaining or increasing range of motion

Manufacturer Details	Address	Certificate number(s)
Restorative Therapies Inc	1434 Fleet Street Baltimore, MD, 21231 United States Of America	

### **ARTG Standard Conditions**

The above Medical Device Included Class IIa has been entered on the Register subject to the following 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.

### **Products Covered by This Entry**

1. RT200 FES elliptical ergometer, RT300 FES cycle ergometer, RT600 FES stepper ergometer -Stimulator, evoked response, electrical

## **Product Specific Conditions**

· No specific conditions have been recorded against this entry.

Therapeutic Goods Administration PO Box 100. Woden ACT 2606 Australia

Phone: 1800 020 653 Email: info@tga.gov.au ARTG Identifier: 176355 ARTG Start Date: 6/10/2010