

### **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- Physical therapy electrical stimulation system, line-powered

ARTG Identifier 284186
ARTG Start date 5/01/2017

Product Category Medical Device Included Class IIa

**GMDN** 46571

GMDN Term Physical therapy electrical stimulation system, line-powered

**Intended Purpose** Xcite is intended for general rehabilitation for:

1. Relaxation of muscle spasms

2. Prevention or retardation of disuse atrophy

3. Increasing local blood circulation

4. Maintaining or increasing range of motion

5. Neuromuscular re-education

6. immediate post surgical stimulation of calf muscles to prevent venous

thrombosis

| Manufacturer Details      | Address   | Certificate number(s) |
|---------------------------|---|-----------------------|
| Restorative Therapies Inc | 1434 Fleet Street<br>Baltimore, MD, 21231<br>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. Physical therapy electrical stimulation system, line-powered

### **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: 284186 ARTG Start Date: 5/01/2017