

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 6.6 of Schedule 3 of the Australian *Therapeutic Goods (Medical Devices) Regulations 2002*.

Manufacturer's Name: Restorative Therapies, Inc
Business Address: 1434 Fleet St
Baltimore, MD 21231
USA
Medical Device(s): Xcite Functional Electrical Stimulation System
Classification: Class IIa
GMDN Code and Term: 46571 Physical therapy electrical stimulation system, line-powered
Scope of Application: All devices

Each kind of medical device to which the declaration of conformity procedures applies, not requiring assessment by Secretary have also been applied to the device. Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures.

Product Quality Management System Certificate:
SGS United Kingdom Ltd
Certificate US15/842321

Standards Applied: ISO13485:2003
EN ISO 13485:2012

Authorised Signatory:



Andrew Barriskill, CEO
Name, Position

January 5, 2017
Date