## 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 So	chedule 3 of the Australian	Therapeutic Goods	(Medical Devices)
Regulations 2002			

Manufacturer's Name: Restorative Therapies, Inc

1434 Fleet St Baltimore, MD 21231

Medical Device(s): RT200 Motorized Functional Electrical Stimulation Elliptical Ergometer

Classification: Class IIa

**Business Address:** 

GMDN Code and Term: 32516 Stimulator, evoked response, electrical

Scope of Application: All devices

Each kind of medical device to which the declaration of conformity procedures applies, not requiring assessment by Secretary have 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: ISO 13485:2003 EN ISO 13485:2012

Authorised Signatory:

, CEO March 25, 2016
Name, Position Date