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

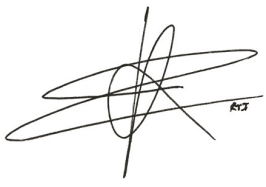
Scope of Application: All devices

Each kind of medical device to which the declaration of conformity procedures applies, the production quality assurance procedures 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: *ISO 13485:2016*
EN ISO 13485:2016

Authorised Signatory:



Thierry Houdayer, QA&R manager
Name, Position

May 29, 2019
Date