

# 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):** *RT300 Motorized Functional Electrical Stimulation Cycle Ergometer*

**Classification:** *Class IIa*

**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

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Name, Position

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March 25, 2016  
Date