

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: *8098 Sandpiper Circle
Suite M
Nottingham, MD 21236
USA*

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



Edward Burkot, QA&R manager
Name, Position

07 DEC 2022
Date