

EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer:

Restorative Therapies, Inc
1434 Fleet St
Baltimore, MD 21231
USA



Declares that the medical device described hereafter:

Product Name: **RT300**
Model Numbers: FA100052, FA102011, FA104581, FA109080, FA216769,
FA217786, FA217787, FA217791, FA218039, SA105419
Description: Functional electrical stimulation motorized cycle ergometer

has been classified as Class IIa, Council Directive 93/42/EEC, Annex IX, Rule 9, and are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC,

is subject to the procedure set out in Annex V of Council Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of Notified Body Number 1639, SGS Belgium NV, SGS House, Noorderlaan 87 – 2030 Antwerpen, under certificate US15/842321.

Authorized Representative:

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands
Tel: (+31) 70 345 8570
Fax: (+31) 70 346 7299

American Contact:

Restorative Therapies, Inc
1434 Fleet St
Baltimore, MD 21231
USA
Tel: (+1) 800 609-9166
Fax: (+1) 410 878-2466

Signed for and on behalf of Restorative Therapies, Inc
Baltimore, 16 December 2019

A handwritten signature in black ink, appearing to be 'Thierry Houdayer', with a small 'KH' mark below it.

Thierry Houdayer, QA&R Manager

	RT300 Declaration of Conformity EC		Project: RT300	
	1 of 1		Version: 11	EN101263