EC Declaration of Conformity

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

The medical device described hereafter:
Product Name: RT600
Description: Functional electrical stimulation motorized upright cycle ergometer

Manufacturer	Restorative Therapies, Inc 8098 Sandpiper Circle Suite M Nottingham, MD 21236 USA
Manufacturer SRN	US-MF-000023084
Authorized EU Representative	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands Tel: (+31) 70 345 8570 Fax: (+31) 70 346 7299
Product Code/Catalog Number	Name/Description
FA211509	RT600-SL
Classification and Rules	Class IIa, Council Directive 93/42/EEC, Annex IX, Rule 9
Basic UDI-DI	*+M720XXXXXXXX0T*
Intended Purpose	This device is intended for general rehabilitation for: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing of local blood circulation • Maintaining of increasing range of motion
Common Specifications	N/A
Technical Standards ref:	Safety: IEC 60601-1, 2-10 EMC: EN60601-1-2, 2-10 NRTL/CSA listing
EC Certificate	US19/819943556
The above listed medical device(s) are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All devices are designed, manufactured, tested, and released for sale in accordance with the technical documentation. This declaration 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.

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Signed for and on behalf of Restorative Therapies, Inc
Effective Date:, 07 DEC 2022

Edward Burkot, QA&R Manager