

## EC Declaration of Conformity

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

The medical device described hereafter:

Product Name: RT300

Description: Functional electrical stimulation motorized 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 Westervoortsedijk 60 6827 AT Arnhem, Netherlands Tel: (+31) 70 345 8570 Fax: (+31) 70 346 7299
Product Code/Catalog Number	Name/Description
FA100052	RT300-SL
FA102011	RT300-SLA
FA104581	RT300-SLSA
FA109080	RT300-LSA
FA216769	RT300-SLP
FA217786	RT300-SLA Supine
FA217787	RT300-SLSA Supine
FA217791	RT300-LA supine
SA105419	UE FES existing RT300-SL
SA218657	Upgrade, Supine SLA to SLSA
SA220039	Upgrade, Supine LA to SLA
SA220040	Upgrade, Supine LA to SLSA
Classification and Rules	Class IIa, Council Directive 93/42/EEC, Annex IX, Rule 9
Basic UDI-DI	*+M720XXXXXXXXX0U*
Intended Purpose	The devices are intended for general rehabilitation for: <ul style="list-style-type: none"> <li>• Relaxation of muscle spasms</li> <li>• Prevention or retardation of disuse atrophy</li> <li>• Increasing of local blood circulation</li> <li>• Maintaining of increasing range of motion</li> </ul>
Common Specifications	N/A

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Technical Standards ref:	Safety: EN60601-1, -2-10, -1-11 (excluding models FA217787, FA217786, FA217791, and FA218039)  EMC: EN60601-1-2, EN60601-2-10  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.	



Signed for and on behalf of Restorative Therapies, Inc,  
Effective Date: 02 Feb 2024

A handwritten signature in blue ink, appearing to read 'E. Burkot'.

Edward Burkot, QA&R Manager