

## EC Declaration of Conformity

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

The medical devices described hereafter:

Product Name: RT200

Description: Functional electrical stimulation motorized elliptical 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
FA109136	RT200-SLSA
FA211762	RT200-SLA
Classification and Rules	Class IIa, Council Directive 93/42/EEC, Annex IX, Rule 9
Basic UDI-DI	*+M720XXXXXXXXX0V*
Intended Purpose	This device is 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
Technical Standards ref:	Safety: IEC 60601-1:2012, 2-10:2012 EMC: EN60601-1-2:2001, 2-10:2012 Home Health: IEC 60601-1-11:2010 Risk: EN ISO14971:2012 Software: IEC62304:2006, AMD1-2015 Symbols: EN ISO15223-1:2016 Usability: EN62366-1:2015
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	

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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: 07 DEC 2022

Edward Burkot, QA&R Manager



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