

## EC Declaration of Conformity

The medical device described hereafter:

Product Name: Xcite Clinical Station

Description: Functional electrical stimulation system

Manufacturer	Restorative Therapies, Inc 8098 Sandpiper Circle Suite M Nottingham, MD 21236 USA
Manufacturer SRN	US-MF-000023084
Authorized Representative	Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands Tel: (+31) 70 345 8570 Fax: (+31) 70 346 7299
Product Code/Catalog Number	Name/ Description
FA216218	Xcite Clinical Station
Classification and rules	Class IIa, Council Directive 93/42/EEC, Annex IX, Rule 9
Basic UDI-DI	*+M720FA2162180*
Intended Purpose	The 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> <li>• Neuromuscular re-education</li> <li>• Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis</li> </ul>
Common Specifications	N/A
Technical Standards Ref:	Safety: EN60601-1, -2-10, -1-11 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.

EC Declaration of Conformity




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

Signed for and on behalf of Restorative Therapies, Inc



Edward Burkot  
Quality & Regulatory Manager

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