

Contract Number: 710292

Certificate: USTC/16/FAI/00200

SGS Reference: 625404/01

Certified Product:

Xcite System

Model(s):

Xcite Clinical

Technical Data:

100-240 V, 50/60 Hz, 1.3 A or internally powered

Class II or internally powered, detachable power supply cord (when Class II), mobile (with cart), portable (without cart), Type BF applied parts, IPX0



Certificate Holder

Manufacturer

Restorative Therapies, Inc.
1434 Fleet Street
Baltimore, MD 21231
USA

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1434 Fleet Street
Baltimore, MD 21231
USA

The product is certified according to ISO/IEC Guide 17067, *Conformity assessment — Fundamentals of product certification, System 3*, and in accordance with the standards indicated on page 2

This certificate is valid until 15 August 2019 unless the standard in question has been amended or superseded with significant changes in requirements, in which case, SGS has the right to shorten the validity of the certificate based on the legislation. This certificate includes the right to use the **SGS Product Certification Mark** under the condition that changes (if any) will be checked at SGS before the product is brought onto market and that the conditions for the **SGS USTC Certification Program** are met.

Authorized by

Effective date: 15 August 2016
Suwanee, GA

Paul Krauss
Certification Manager

Consumer Testing Services, a division of SGS North America Inc
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**Standard for Medical Electrical Equipment – Part 1: General Requirements
for Basic Safety and Essential Performance
ANSI/AAMI ES60601-1:2005 + A1: 2012 + C1:2009 +A2:2010
CAN/CSA C22.2 No.60601-1:14**

**Part 2-10: Particular Requirements for the Basic Safety and Essential
Performance of Nerve and Muscle Stimulators
CAN/CSA-C22.2 No. 60601-2-10:2014, 2nd Ed.
IEC 60601-2-10: 2012, 2nd Ed.**

**Part 1-11: Collateral Standard: Requirements for medical electrical
equipment and medical electrical systems used in the home healthcare
environment,
ANSI/AAMI HA60601-1-11: 2011
CAN/CSA-C22.2 No. 60601-1-11:2011**

