Health Canada Santé Canada

Declaration of Conformity

DEMONSTRATION OF CONFORMITY WITH RECOGNIZED STANDARDS TO SATISFY THE SAFETY AND EFFECTIVENESS REQUIREMENTS OF THE CANADIAN MEDICAL DEVICES REGULATIONS

Name of the medical device as it appears on the label: RT50

Name of the Manufacturer of the medical device: Restorative Therapies Inc

1. List of recognized standard(s) applicable in part or in whole to this Medical Device:

Full name of Standard(s) as stated on the *TPD Recognized Standards List*
IEC 60601-1, EN60601-1-2, EN60601-2-10, EN55011, Group 1, Class B, EN6100-3-2, EN6100-3-3

In the case where only specific parts or Sections of a recognized standard apply to the device, *Sections 2 through 7 must be completed.*

In the case where all parts and Sections of a recognized standard apply to the device, *Section 5 through 7 must be completed.*

2. In the case where only specific parts or Sections of a recognized standard apply to the device, note the requirements that are not applicable to the medical device:

Recognized Standard(s)	**Inapplicable Requirements of the Recognized Standard**

Canada

3. In the case where only specific parts or Sections of a recognized standard apply to the device, note the deviations from the recognized standard(s). For example: To meet requirements of other Federal or Provincial legislation in Canada.

Name of Recognized Standard	Deviation

4. In the case where a standard has been adapted, note the requirements of the standard(s) have been adapted for application to this medical device. For example: In the case of a standard that offers alternative methods, specify which method has been followed.

Standard	Adapted Section(s)

5. The medical device which was tested against the recognized standard(s) is identical to the medical device intended to be marketed in Canada:

Yes ✓ No □

If the answer above is No, the difference(s) between the tested medical device and the medical device intended to be marketed in Canada are as follows:

_____
_____
_____
_____
_____

Given the difference(s) between the tested medical device and the medical device intended to be marketed in Canada, the application of the recognized standard(s) is justified for the following reason(s):

_____
_____

6. An independent testing laboratory or certification body was used to determine the conformance of the medical device with the recognized standard(s):

Yes ✓ No □

If the answer to the above is Yes, the name and address of the testing laboratory or certification body and their accreditations are as follows:

Name and Address of Testing Laboratory or Certification Body	International, National or Provincial Accreditations of the Testing Laboratory or Certification Body
Washington Labs 7560 Lindbergh Drive Gaithersburg, Maryland 20879	This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated January 2009*).

7. As a senior official of the manufacturer, having responsibility for the regulatory compliance of the medical device with the requirements of the Canadian *Medical Devices Regulations* and this Declaration of Conformity, I hereby declare that the information I have provided in support of the safety and effectiveness of the medical device to be true and accurate.

I also acknowledge that any false statement made with respect to the conformity of the medical device with an applicable recognized standard(s), or a determination by Health Canada that the medical device does not conform to the requirements of the recognized standard(s), could result in the suspension of any medical device licence which has been issued for the medical device subject of this Declaration of Conformity.

Name of Senior Official Andrew Barriskill

Title of Senior Official CEO

Signature of Senior Official 

Date: 26 April 2013