



# Declaration of Conformity

This form is intended to demonstrate conformity with recognized standards to support the safety and effectiveness requirements of the Canadian medical devices regulations.

To aid in completion of this form, consult the [List of recognized standards for medical devices](#).

1. Name of the device (as it appears on the label)		
Device name:		
2. Name of the manufacturer (as it appears on the label)		
Company name:		
3. List of recognized standard(s)		
List the recognized standard(s) to which conformity is being declared. Include all standards that apply, in part or in whole.		
<b>Note:</b> If the standard is not the latest published version, additional rationale must be provided in the submitted documentation associated with the standards to which you have declared conformity.		
Full name of Standard(s) as stated on the List of Recognized Standards for Medical Devices	Year and edition used for conformity	Is this the latest published version (yes/no)
If you require additional rows please use <b>Appendix 1</b> .		

<b>4. Requirements of the Recognized Standard that are not applicable</b>	
In the case where only specific parts or sections of a recognized standard apply to the device, list the requirements that are not applicable to the medical device.	
<b>Note:</b> If you have adapted or deviated from a standard during the testing of your medical device(s), detailed information about these changes must be provided in the submitted documentation associated with the standards to which you have declared conformity.	
Recognized Standard(s)	Requirements of the Recognized Standard that are not applicable
If you require additional rows please use <b>Appendix 2</b> .	





## 7. Attestation

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:	Title of Senior Official:
Signature:	Date (yyyy-mm-dd):





