Draft Declaration of Conformity

DEMONSTRATION OF CONFORMITY WITH CONSENSUS 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:	
Name of the Manufacturer of the medical device	

1. List of standard(s) applicable to this Medical Device to which conformity is being declared :

a. Recognized Standards

Full name of Standard as stated on the *TPD Recognized Standards List* including year and/or edition	Were all the requirements of the standard met?	Location in application of *Note 1* information, if applicable	Was the medical device which was tested against the recognized standard identical to the medical device intended to be marketed in Canada?	Location in application of *Note 2* information, if applicable
	Yes or No* ***See Note 1 below***		Yes or No* ***See Note 2 below***	
	Yes or No		Yes or No	
Insert more rows as required				

b. Other standards

Full name of Standard including year and/or edition	Were all the requirements of the standard met?	Location in application of *Note 1* information, if applicable	Was the medical device which was tested against the recognized standard identical to the medical device intended to be marketed in Canada?	Location in application of *Note 2* information, if applicable
	Yes or No* ***See Note 1 below***		Yes or No* ***See Note 2 below***	
	Yes or No		Yes or No	
Insert more rows as required				

Note 1*: If all the requirements of the standard were not met, the following information must be provided in the application:*
List the sections of standard that

a. *Are not applicable to the device, and/or*
b. *have been adapted, and/or*
c. *were deviated from to meet national or provincial regulations*

Note 2*: If the device used in testing was not identical to the device intended to be marketed in Canada, the following information must be provided in the application:*

a. *The difference between the tested medical device and the medical device intended to be marketed in Canada, and*
b. *a justification that the device differences do not affect the claim of conformity to the standard*

2. Identification of Testing Laboratories and Certification Bodies

An independent testing laboratory or certification body was used to determine the conformance of the medical device with the listed 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:

Full name of Standard	Name and Address of Testing Laboratory or Certification Body	International, National or Provincial Accreditations of the Testing Laboratory or Certification Body

3. Declaration

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.

4.

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 of Senior Official _____

Date _____