September 22, 2006

# NOTICE

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To: All Stakeholders

Re: Updated guidance on the Recognition and Use of Standards under the Medical Devices Regulations

Please find attached the updated guidance document on the Recognition and Use of Standards under the Medical Devices Regulations. This document replaces the previous document entitled "*Policy on Recognition and Use of Standards under the Medical Devices Regulations*".

With this new update, the list of recognized standards and the Declaration of Conformity form have been made into separate documents. The new documents can be found as follows:

| Document | Location |
|---|---|
| Guidance Document: Recognition and Use of Standards under the Medical Devices Regulations | http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html#guidance_devices |
| Form: Declaration of Conformity | http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/index_e.html |
| List of Recognized Standards | http://www.hc-sc.gc.ca/dhp-mps/md-im/standards-normes/md_rec_stand_im_norm_lst_e.html |

As part of this update, several new standards have been added to the list of recognized standards and some clarification has been added to the guidance document regarding information that Health Canada may request in addition to a Declaration of Conformity.

Recently, the Medical Device Bureau of Health Canada has received a number of questions regarding what data must be provided for medical device licence applications when the manufacturer provides a Declaration of Conformity to a given standard. If the recognized standard describes test methods, but does not include specific pass/fail criteria, the manufacturer must provide test results along with appropriate interpretations and conclusions drawn from them in a manner that is consistent with the risk classification of the device. If the manufacturer does not provide this supporting data along with the Declaration of Conformity, Health Canada may cite this as a deficiency when screening the application, or request additional information after the scientific review. For performance standards where specific test methods and pass/fail criterion are clearly defined, supporting information is generally not required beyond a Declaration of Conformity stating that the full scope of the standard that has been met.

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An example of a test method standard is ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing). Within the scope of the document, there are a number of approaches that may be taken that are consistent with the standard in demonstrating adequate biocompatibility. As the standard does not provide specific criteria to be met, the manufacturer must provide data that indicates the tests performed, the results obtained, and an interpretation of the results with conclusions drawn consistent with the risk classification of the device.

An example of a performance standard is ISO 5841-3 (Low-profile connectors [IS-1] for implantable pacemakers). This standard fully defines the dimensions and tolerances of a low profile connector for an implantable pacemaker. There are certainly other aspects of function that must be demonstrated that are outside the scope of the standard (such as biocompatibility, and general pacemaker function) but a declaration of conformity is sufficient to demonstrate the safety and effectiveness of the mechanical and electrical aspects of the low profile connector.

For further information on this guidance, the Declaration of Conformity Form, or the List of Recognized Standards, please contact:

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