1. **Purpose**

To describe the requirements for compliance with the Canadian Medical Device Regulations for device and establishment licensing and distribution of our medical devices intended for sale in the Canada.

1. **Scope**

This procedure pertains to compliance with the Canadian Medical Device Conformity Assessment System for all medical device related products and their accessories which are intended for distribution in the Canada.

1. **General**
   1. **Definitions**

**CMDR** **–** Canadian Medical Device Regulations (SOR 98-282)

**CMDCAS** **–** Canadian Medical Device Conformity Assessment System

**QMS –** Quality Management System

* 1. **Responsibilities**
     + **The Quality and Regulatory Affairs** are responsible for adherence to the Canadian Medical Device Regulations and associated directives and international standards pertaining to medical device distribution in Canada.
  2. **Equipment and Materials –** N/A
  3. **Safety Precautions –** N/A
  4. **Training Requirements –** Quality and Regulatory Affairs are required to be trained to this procedure and the training documented.
  5. **References**

**SOR/98-282** – Canadian Medical Device Regulations

**ISO 13485** – Medical Device Quality Management Systems

1. **Procedure**
   1. The company maintains a Quality Management System compliant with ISO 13485, the Canadian Medical Device Regulations, and other relevant standards and directives that support product creation and distribution. The QMS is certified by a Recognized Registrar that is recognized by Canada to complete MDSAP audits including the specific regulatory requirements of Canada.
      * The Recognized Registrar will be notified of any plans for substantial changes to the QMS or where the product range covered by the scope of registration will be revised.
      * Where the ISO certificate is reissued or revised to reflect changes within the scope of coverage, a new/revised ISO certificate will be sent to Health Canada within 30 days of its issuance.
   2. The company will maintain a valid establishment license with Health Canada and valid medical device licenses for all products distributed in Canada. Where a distributor is used, the distributor will maintain appropriate registrations with the Canadian government to lawfully import and distribute medical devices (Classes I, II, III and IV).
   3. The company will obtain a new (or amended) medical device license prior to the import or sale of a new (or significantly modified) device to Canada, with the exception of Class I medical devices, which do not require device licensing.
      * Product to be licensed will be designed and manufactured to be safe and effective and meet the requirements of Sections 10-20 of the CMDR.
      * Where significant changes to product or product offering occur, the company will file the appropriate documentation (e.g. amendment, fax back form, etc.) with Health Canada.
      * If required, the company will submit requested documentation that helps support that product to be licensed meets appropriate safety and efficacy requirements.
        + As required, device instructions will be made available in English and/or French
      * The company will confirm the accuracy of product documentation for actively distributed products with Health Canada during annual renewal of medical device licenses.
        + Reportable, non-significant changes (documentable) will be communicated to Health Canada at this time.
   4. The QMR will submit the necessary documentation (data and forms) to meet the scope of the Canadian regulatory requirements for medical devices. The company has included requirements for compliance to the Canadian Device Regulations in our Quality System Procedures for Complaint Handling, Medical Device Reporting, Product Recall (Vigilance), Post Market Surveillance and other procedures required for compliance to the CMDR.
      * The company will work with Canadian distributor(s) to support timely and effective complaint handling and vigilance activities.
2. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 00 | QP-0030 |  |  | Initial release of the Canadian Medical Device Regulations Procedure |