LICENSING A MEDICAL DEVICE IN CANADA

OVERVIEW OF SUBMISSION AND REGULATORY REQUIREMENTS

N.B. All these documents should be kept on record by the responsible parties, even if they are not part of the submission package.

Required Submission Documents					Regulatory Requirements				
Responsible Parties	**Manufacturer**			**All parties engaged in importation or sales activities**	**Manufacturer Importer Distributor**			**Manufacturer Importer**	
Documentation	**Medical device licence application and fee form**	**Objective evidence for safety & effectiveness**	**Quality Management System (QMS) Certificate**	**Compliant label**	**Complaint Handling Record**	**Distribution Records**	**Must hold an active establishment licence**	**Recall Notice**	**Mandatory Problem Preliminary and Final Report**
Class I	Requires Medical Device Establishment Licence			✔	✔	✔	✔	✔	✔
Class II	✔	Provide attestation	✔	✔	✔	✔	Exempt if holding an active medical device licence	✔	✔
Class III / IV	✔	✔	✔	✔	✔	✔	Exempt if holding an active medical device licence	✔	✔

QUICK REFERENCES FOR THE MEDICAL DEVICE REGULATIONS

- SAFETY AND EFFECTIVENESS Sections 10 to 20
- DISTRIBUTION RECORDS Sections 52 to 58
- MANDATORY PROBLEM REPORTING Sections 59 to 62
- MEDICAL DEVICE ESTABLISHMENT LICENCE (MDEL)
- LABELLING Sections 21 to 23
- RECALL REQUIREMENTS Sections 63 to 65
- APPLICATION & FEE FORMS
- Quality Management Certificate

For additional information please contact The Medical Devices Bureau (MDB)