Health Canada Santé Canada

Application Form for Revised Investigational Testing Authorization (ITA)

*denotes a mandatory field

Part 1 – Revision to Investigational Testing Information

1. Please indicate the Investigational Testing Authorization Application Number that is to be revised. *

2. Please check off all the modifications that have been made to the last authorization. *

	Types of Revisions	
Changes to Device Details	A change to the classification of a device	☐
	A change in the manufacturer's name or address	☐
	A change to device name (s)	☐
	A change to the intended use of the device	☐
	A change to the design or performance specifications (including software changes)	☐
	A change in device materials	☐
	A change to sterilization	☐
	A change to the labeling	☐
	A change in manufacturing process, facility, equipment or quality control procedures	☐
	Any change which could affect the safety and effectiveness of the device	☐
	Addition, deletion, or change in device components or associated model/catalogue numbers	☐
Change to Study Details	A change to protocol details	☐
	A change to Informed Consent Form (ICF)	☐
	A change to the number of study subjects in Canada	☐
	A change to the duration of the study	☐
	A change to the number of device units requested	☐
Change to Institutional	Addition or deletion of institution(s)	☐
	Addition or deletion of investigator(s)	☐
	Class III & IV ONLY Updated institutional approval information (REB) with reference to the most current protocol and informed consent forms	☐

Canada

Part 2 – Manufacturer Information

A) Manufacturer Mailing Address ☐ No Changes

3. Manufacturer Name (Full Legal Name – No Abbreviations)			
4. Street Address/Suite/Post Office Box			
5. City	6. Prov./State	7. Country	8. Postal/Zip Code
9. Contact Name	10. Title	11. Telephone Number	12. Fax Number
13. Language Preferred ◯ English ◯ French	14. Email		

B) Regulatory Correspondence Mailing Address ☐ No Changes

15. Manufacturer Name (Full Legal Name – No Abbreviations)			
16. Street Address/Suite/Post Office Box			
17. City	18. Prov./State	19. Country	20. Postal/Zip Code
21. Contact Name	22. Title	23. Telephone Number	24. Fax Number
25. Language Preferred ◯ English ◯ French	26. Email		

Part 3 – Changes to Device Information

27. Device Name – as it appears on label. This is the device name for which the Authorization will be issued.

☐ No Changes

28. Intended Use of Device. Please provide the change in the intended use statement to indicate the disease(s) or condition(s) the device is intended to diagnose, treat, prevent or mitigate.

☐ No Changes

Part 4 – Changes/Updates to Research Ethics Board (REB)/Ethics Committee (EC)/Investigational Research Board (IRB)

29. Are you providing information regarding Research Ethics Board (REB)/Ethics Committee (EC)/Investigational Research Board (IRB)? *

◯ Yes ◯ No Changes

30. If you are providing information regarding Research Ethics Board (REB), please include the institution protocol number and version and/or date below in **Sections 32-36**:

Note: It is required that you provide a clean and redlined version of the protocol and/or ICF changes along with a summary of the changes. Have you provided this?

◯ Yes ◯ No

31. Investigational Sites Name and Address	32. Investigator	33. REB Approved Protocol Version and Date	34. REB Approved ICF Version and Date	35. Is this a new investigator/site?
				◯ Yes ◯ No
				◯ Yes ◯ No
				◯ Yes ◯ No

Part 5 – Changes to Device Details ☐ No Changes

36. Please provide the following information for each device, component, part or accessory to be changed from the previous authorization by completing S**ections 37-40**. Please note: **Only device details which have been modified** from the previous authorization should be included in the table below.

	37. Name of Device, Components, Parts and/or Accessories as per Product Label	38. Model or Catalogue Number	39. Total Number of Units Requested	40. Global Medical Device Nomenclature (GMDN)	Health Canada Use Only Device Identification Number
Addition					
Deletion	**37. Name of Device, Components, Parts and/or Accessories as per Product Label**	**38. Model or Catalogue Number**	**39. Total Number of Units Requested**	**40. Global Medical Device Nomenclature (GMDN)**	**Health Canada Use Only** **Device Identification Number**

Part 6 – Changes to Protocol Identification ☐ No Changes

41. Protocol Title:

42. Protocol Version and Date:

43. Total Number of Patients in the Study (Canadian Sites ONLY):

44. Total Duration of Study:

45. Duration of the Study Enrolment Phase:

46. Study Objectives:

Part 7 – Supporting Information/Evidence to be submitted with an Investigational Testing Authorization Application

47. Please check all items that are included in the submission to support the requested revision to an investigational testing authorization.

Required for ALL Applications (Class II, III, and IV)
☐ Device Description & Design Philosophy
☐ Previously licensed IT/SAP authorized in Canada
☐ Device Labeling
☐ List of Primary Investigators(s)
☐ Institution name(s) and address(es)
☐ Study Protocol Document (Date and Version)
☐ Informed Consent Form (ICF) (Date and Version)
☐ **Recommended** for Class II: Standards and Declaration of Conformity (DoC)
Required for Class III and Class IV ONLY (May include for Class II devices if necessary)
☐ Marketing History
☐ Risk Assessment
☐ Animal Studies
☐ Clinical Studies
☐ List of Primary Investigator(s) and their Curriculum Vitaes (CVs)
☐ Signed Investigator Agreement(s)
☐ Standards and Declaration of Conformity (DoC)
☐ Verification and Validation: device design (E.g. mechanical, electrical); performance; shelf life; sterilization; bioburden, pyrogenicity; software; packaging stability; and, biocompatibility.
☐ Research Ethics Board (REB)/Ethics Committee (EC)/Investigational Research Board (IRB) approval. This must reference (date and version) the submitted protocol and ICF documents to demonstrate the REB approval.

Part 8 – Attestations and Signatures

I, as a senior official of the manufacturer named in **Section 9** of this application, hereby attest that I have direct knowledge of the items checked above and declare that these identified statements are true and that the information provided in this application and in any attached documentation is accurate and complete.

Where a person is named in **Section 21** of this application, I hereby authorize that person to submit this application to the Minister on my behalf. I further authorize the Medical Devices Bureau to direct all correspondence relating to this application to the person named in **Section 21**.

48. Name: *	49. Title:
50. Signature:	51. Date (YYYY-MM-DD):