Health Canada Santé Canada

Application for New Investigational Testing Authorization (ITA)

* denotes a mandatory field

Part 1 – Manufacturer Information

A) Manufacturer Mailing Address

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

B) Regulatory Correspondence Mailing Address

◯ Same as Manufacturer ◯ Other (specify below):

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

Canada

Part 2 – Device Information

25. Risk Classification of Device *
◯ Class II ◯ Class III ◯ Class IV

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

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

28. Device History. Please indicate whether the device subject to this application has been previously authorized for sale and/or importation in Canada under the Investigational Testing or Special Access provisions of the Medical Device Regulations. *

◯ Yes ◯ No

If yes, please provide reference to the application number(s), device name(s), and device identification number(s) as per the authorization by filling out **Sections 29-32** for each related application.

29. ITA/SAP Application Number	30. Device Name	31. Catalogue/Model Number	32. Authorization Date (YYYY-MM-DD)

33. Device Type *
◯ Single Device ◯ Medical Device Group ◯ Medical Device Group Family ◯ Medical Device Family
◯ Test Kit ◯ System

34. Is this device a near patient *in vitro* diagnostic device (IVDD)?* ◯ Yes ◯ No

35. Is this device intended to be sold for home use?* ◯ Yes ◯ No

36. Please provide the following information for device details, where applicable for each component device, part or accessory in **Sections 37-40**.

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 3 – Device Containing a Drug (Note: this question does not apply to In Vitro Diagnostic Devices (IVDDs))

41. Does this device contain a drug?* ◯ Yes ◯ No

If yes, please proceed to **section 42**.

If no, please proceed to **section 46**.

42. Does it have a Drug Identification Number (DIN) issued by Health Canada? ◯ Yes ◯ No

If yes, please provide the DIN(s):	

Please fill out **Sections 43-45** for each Active Pharmaceutical Ingredient (API) that is being used.

Drug 1.

43. Active Pharmaceutical Ingredient(s) (APIs):

44. Please confirm the compliance to pharmacopeia or compendia standards by checking off the box below and please specify.

☐ Compliance to Pharmacopeia or Compendia Standards and specify:

☐ Not applicable

45. Master File (MF) Number and Applicant Name:

Drug 2.

43. Active Pharmaceutical Ingredient(s) (APIs):

44. Please confirm the compliance to pharmacopeia or compendia standards by checking off the box below and please specify.

☐ Compliance to Pharmacopeia or Compendia Standards and specify:

☐ Not applicable

45. Master File (MF) Number and Applicant Name:

46. Is this device being used in a drug study? ◯ Yes ◯ No

If yes, please provide the Clinical Trial Application (CTA) Number: | | | | | | |

If CTA number is unknown, please check the box below to confirm that a CTA will be submitted/has been submitted to Health Canada.

☐ Will provide CTA number prior to issuance of an ITA.

Part 4 – Device Containing Biological Material

47.

a) Does this device consist of a recombinant material?* ◯ Yes ◯ No

b) Does this device contain, or is it produced using any animal or human sourced material?* ◯ Yes ◯ No

If yes to either question, please proceed to **Section 48**.

If no to both questions, please proceed to **Section 58**.

48. Does it have a Drug Identification Number (DIN) issued by Health Canada? ◯ Yes ◯ No

If yes, please provide the DIN(s):

Please fill out **Section 49-57** for each recombinant material that is being used.

Biological Material 1.

49. Name of Biological Material	50. Drug Substance	51. Dosage	52. Units

53. Master File (MF) number and Applicant Name:

54. Country of Origin (for animals only):

55. Species (e.g.: bovine, ovine, etc.):

56. Tissue Type (e.g., bone, heart valve, skin and hair):

57. Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):

Biological Material 2.

49. Name of Biological Material	50. Drug Substance	51. Dosage	52. Units

53. Master File (MF) number and Applicant Name:

54. Country of Origin (for animals only):

55. Species (e.g.: bovine, ovine, etc.):

56. Tissue Type (e.g., bone, heart valve, skin and hair):

57. Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):

Biological Material 3.

49. Name of Biological Material	50. Drug Substance	51. Dosage	52. Units

53. Master File (MF) number and Applicant Name:

54. Country of Origin (for animals only):

55. Species (e.g.: bovine, ovine, etc.):

56. Tissue Type (e.g., bone, heart valve, skin and hair):

57. Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):

58. Is this device being used in a biologic study? ◯ Yes ◯ No

If yes, please provide the Clinical Trial Application (CTA) number: | | | | | | |

b) If CTA number is unknown, please check the box below to confirm that a CTA will be submitted/has been submitted to Health Canada

☐ Will provide CTA number prior to issuance of an ITA

Part 5 – Protocol Identification

59. Protocol Title* :	
60. Protocol Version and Date* :	
61. Total Number of Patients in the Study (Canadian Sites ONLY)* :	
62. Total Duration of Study* :	
63. Duration of the Study Enrolment Phase* :	

64. Study Objectives* :

Part 6 - Supporting Information/Evidence to be submitted with an Investigational Testing Authorization Application

65. Please check all the items that are included in the submission.
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

66. I, as a senior official of the manufacturer named in **Section 7** 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 19** 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 19**.

67. Name: *	68. Title:
69. Signature:	70. Date (YYYY-MM-DD):