Health Canada Santé Canada

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Application form for medical device clinical trials under the *Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations*

*** denotes a mandatory field**

Part 1 - Contact Information

A) Applicant Mailing Address*

1. Applicant 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 O English O French	
12. Email			

B) Manufacturer Mailing Address* ☐ Same as Applicant

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 O English O French	
24. Email			

Canada

C) Importer Mailing Address* ☐ Same as Manufacturer			
25. Importer Name (Full Legal Name – No Abbreviations)			
26. Street Address/Suite/Post Office Box			
27. City	28. Prov./State	29. Country	30. Postal/Zip Code
31. Contact Name	32. Title		
33. Telephone Number	34. Fax Number	35. Language Preferred ○ English ○ French	
36. Email			

Part 2 - Device Information

37. Risk Classification of Device * ○ Class II ○ Class III ○ Class IV

37a. Specify the rule and sub-rule used to arrive at the classification based on the Classification Rules set out in Schedule 1 of the *Medical Devices Regulations* (further details can be provided in the submission).

Additional information to assist with classification can be found in the Guidance Document: Guidance for the Risk-based Classification System for In Vitro Diagnostic Devices (IVDDs), Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs), Guidance for Industry - Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices and/or Guidance Document: Software as a Medical Device (SaMD): Classification Examples.

Rule:

Subrule:

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

39. Intended Use of Device (mandatory for Class III and IV). Please provide the intended use statement indicating the disease(s) or condition(s) the device is intended to diagnose, treat, prevent or mitigate.

40. Device History. Please indicate whether the device subject to this application has been previously authorized for sale and/or importation in Canada under the provisions of the *Medical Device Regulations* (e.g., Investigational Testing Authorization (ITA), Medical Device Licence (MDL), Special Access (SA) authorization), *Interim Order (IO) No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19,* or *Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations.* *

O Yes O 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 41-44** for each related application.

41. ITA/SA/IO/MDL Application Number	42. Device Name	43. Catalogue/Model Number	44. Authorization Date (YYYY-MM-DD)

45. Device Type *

O Single Device O Medical Device Group O Medical Device Group Family
O Medical Device Family O Test Kit O System

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

47. Is this device intended to be sold for home use?* O Yes O No

48. Please provide the following information for device details, where applicable for each component device, part or accessory in **Sections 49-53.**

49. Name of Device, Components, Parts and/or Accessories as per Product Label*	**50. Model or Catalogue Number***	**51. Total Number of Units Requested (for Canadian Sites Only)***	**52. Global Medical Device Nomenclature (GMDN)***	**53. Preferred Name Code (PNC)**

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

54. Does this device contain a drug?* O Yes O No

If yes, please proceed to **section 55**.

If no, please proceed to **section 59**.

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

If yes, please provide the DIN(s):	

Please fill out **Sections 56-58** for each Active Pharmaceutical Ingredient (API) that is being used.

Drug 1.

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

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

O Compliance to Pharmacopeia or Compendia Standards and specify:

O Not applicable

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

Drug 2.

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

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

O Compliance to Pharmacopeia or Compendia Standards and specify:

O Not applicable

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

59. Is this device being used in a drug study? O Yes O 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 obtain CTA number prior to initiation of trial

Part 4 - Device Containing Biological Material

60.

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

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

If yes to either question, please proceed to **Section 61**.

If no to both questions, please proceed to **Section 71**.

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

If yes, please provide the DIN(s):	

Please fill out **Sections 62-70** for each recombinant material that is being used.

Biological Material 1.

62. Name of Biological Material	63. Drug Substance	64. Dosage	65. Units

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

67. Country of Origin (for animals only):

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

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

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

Biological Material 2.			
62. Name of Biological Material	63. Drug Substance	64. Dosage	65. Units
66. Master File (MF) number and Applicant Name:			
67. Country of Origin (for animals only):			
68. Species (e.g., bovine, ovine, etc.):			
69. Tissue Type (e.g., bone, heart valve, skin and hair):			
70. Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):			

Biological Material 3.			
62. Name of Biological Material	63. Drug Substance	64. Dosage	65. Units
66. Master File (MF) number and Applicant Name:			
67. Country of Origin (for animals only):			
68. Species (e.g., bovine, ovine, etc.):			
69. Tissue Type (e.g., bone, heart valve, skin and hair):			
70. Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):			

71. Is this device being used in a biologic drug study? ○ Yes ○ No

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

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

☐ Will obtain CTA number prior to initiation of trial

Part 5 - Protocol Identification
72. Protocol Title* :
73. Protocol Version and Date* :
74. Total Number of Patients in the Study (Canadian Sites ONLY)* :
75. Total Duration of Study* :
76. Duration of the Study Enrolment Phase* :
77. Study Objectives* :
78. Please list any other ITA Application Number that uses the Protocol listed in Section 71:

Part 6 - Institution Information		
79. Clinical Trial Site(s) Name and Address	**80. Qualified Investigator Name**	**81. REB Name and Contact Information (Class III and IV only)**

Part 7 - Supporting information to be submitted with an Application for a Medical Device Clinical Trial under the *Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations*

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

Required for ALL applications (Class II, III, and IV)

- ☐ Device identifier & description of features of the device (design philosophy and performance specifications) *
- ☐ Directions for use
- ☐ Device labels *
- ☐ Institution name(s) and contact information*
- ☐ Study protocol document (Date and Version) *
- ☐ Informed Consent Form (ICF) (Date and Version) *
- ☐ Attestation for post-market oversight*

Required for Class III and Class IV device applications (Optional for Class II devices)

- ☐ Device description & intended use
- ☐ Marketing history
- ☐ Quality, safety and effectiveness information (e.g., bench testing, animal studies, clinical studies, risk assessment)
- ☐ Name of lead qualified investigator and qualifications (academic and/or clinical curriculum vitaes (CV) and evidence of membership in good standing with a health care professional's regulatory body)
- ☐ Signed agreement from lead qualified investigator
- ☐ Standards and Declaration of Conformity (DoC)
- ☐ Research Ethics Board (REB) name and contact information

Part 8 - Attestations and Signatures*	
83. I, the applicant 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.	
84. Name:	85. Title:
86. Signature:	87. Date (YYYY-MM-DD):