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February 22, 1999

To: Medical Devices Stakeholders

Subject: Preparation of an Application for Investigational Testing - Medical Devices

The *Medical Devices Regulations* set out the requirements governing the sale, importation and advertisement of medical devices. The goal of the Regulations is to ensure that medical devices distributed in Canada are safe, effective, and meet quality standards. The Therapeutic Products Programme published these new Regulations in Canada Gazette II in May 1998 and began implementation on July 1, 1998.

This document, titled Preparation of an Application for Investigational Testing -Medical Devices, sets out the Programme's guidance on the above.

The purpose of this guidance document is to assist manufacturers and/or device sponsors in their preparation of the necessary documentation that is required to obtain an authorization for the sale of a device for investigational testing, under the *Medical Devices Regulations*.

For more information on how to prepare an application for investigational testing for non-IVDD medical devices please contact:

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Attachments

Therapeutic Products Programme

OUR MISSION: To ensure that the drugs, medical devices, and other therapeutic products available in Canada are safe, effective and of high quality.

Therapeutic Products Programme
GUIDANCE DOCUMENT

Preparation of an Application for Investigational Testing - Medical Devices

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1	Page 15, Section 7.2, first paragraph : <i>Mandatory Problem Report</i>	<p>Paragraph rewritten.</p> <p>Old paragraph: “ Sections 59 to 62 of the <i>Medical Devices Regulations</i> with respect to mandatory problem reporting apply to devices undergoing investigational testing. The investigator and/or the manufacturer are responsible to notify the Therapeutic Products Programme within 72 hours of any incident that meets the criteria as defined in Subsection 59(1) of the <i>Medical Devices Regulations</i>.”</p> <p>New paragraph: “Sections 59 to 62 of the <i>Medical Devices Regulations</i> with respect to mandatory problem reporting apply to devices undergoing investigational testing. The investigator <u>is</u> responsible to notify the Therapeutic Products Programme <u>and the manufacturer</u> within 72 hours of any incident that meets the criteria as defined in Subsection 59(1) of the <i>Medical Devices Regulations</i>.”</p>

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1.0 Introduction

1.1 Purpose

This guidance document is intended to provide assistance to manufacturers and/or device sponsors in preparing the documentation necessary to obtain an authorization for the sale of a non-IVDD device for investigational testing under the *Medical Devices Regulations*.

All medical devices sold in Canada must meet the safety and effectiveness requirements set out in Sections 10 to 20 of the *Medical Devices Regulations*. The only exceptions to these requirements are devices sold under Part 2 of the Regulations for custom or special access purposes and devices sold under Part 3 for investigational testing purposes. For additional information on the special access program available under Part 2 of the Regulations, refer to the guidance document “How to Apply for Authorization to Obtain Custom-Made or Special Access Devices (GD004).”

1.2 Background

Section 9 of *Medical Devices Regulations* states that all devices sold or offered for sale in Canada must meet the safety and effectiveness requirements of the regulations. There are exceptions for medical devices sold under Parts 2 and 3 of the Regulations.

Part 3 of the regulations will allow for the investigational testing of medical devices in Canada which do not yet meet the safety and effectiveness requirements listed in Sections 10 to 20 of the Regulations. An Authorization for Investigational Testing will not be issued until a manufacturer and/or device sponsor has complied with the requirements of Sections 79 to 88 of the Regulations.

1.3 Scope

This guidance document is intended to aid manufacturers and/or device sponsors in organizing and submitting an application for Investigational Testing Authorization for Class II, III and IV devices. It also provides details on the manufacturers responsibilities when conducting investigational testing using Class I devices.

This document will also assist investigators and institutions involved in the investigational testing of medical devices in Canada to understand their roles and responsibilities in this process.

This document is not applicable to the investigational testing of *in vitro* diagnostic devices (IVDDs) in Canada. Manufacturers and/or device sponsors are referred to the guidance document titled “Preparation of an Application for Investigational Testing - *in vitro* Diagnostics (GD010).” This document is available on the Therapeutics Products Programme (TPP) website at www.hc-sc.gc.ca/hpb-dgps/therapeut.

1.4 Definitions

ADDITIONAL INFORMATION - A written request made under Section 84 for additional information necessary to determine whether the conditions set out in subsection 83(1) have been met.

DEVICE IDENTIFIER - means a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it as different from similar devices.

DEVICE NAME - in respect of a medical device, includes any information necessary for the user to identify the device and to distinguish it from similar devices.

2.0 How to Apply for an Investigational Testing Authorization

2.1 The Application

To apply for an authorization to conduct investigational testing on human subjects in Canada, a manufacturer and/or device sponsor must use the application form in Appendix 1. Appended to this application form will be the necessary supporting records as detailed in Section 81 paragraphs (a) to (k). To facilitate the timely evaluation of these applications it is recommended that the manufacturer provide an executive summary, a table of contents and the discrete chapters appropriate for each class of medical device. The presentation and structure of the investigational testing authorization application should be organized into sections as outlined in Appendix 2.

Applications should be sent to:

Medical Devices Bureau
Therapeutic Products Programme
Room 1605
Statistics Canada Main Building
Postal Locator: 0301H1, Tunney's Pasture
Ottawa, Ontario, K1A 0L2

2.2 Review and Authorization

Following the review of the application, the Minister may issue an authorization to conduct the proposed investigational testing, provided the device can be used without seriously endangering the life or health of patients, users or other persons, the testing is not contrary to the best interests of the patients and the objective of the testing is achievable. All investigational testing carried out in Canada must conform to the principles of the Declaration of Helsinki and the Medical Research Council's "Code of Ethical Conduct for Research Involving Humans - May 1997."

If the documentation provided with the application is not sufficient to enable a determination under Subsection 83(1), then **ADDITIONAL INFORMATION** may be requested under Section 84.

An investigational testing authorization will specify the information listed in Section 83 subsection (2) of the *Medical Devices Regulations*. The authorization will remain valid provided no changes are made to the investigational protocol, the identity of the qualified investigators and the institution where the testing is being conducted and the type of diagnosis or treatment for which the device is sold. The investigational authorization will also specify the number of units of the device which may be sold.

2.3 Changes Made During an Investigational Testing Authorization

If changes are made to the investigational protocol, the identity of the qualified investigators and the institution where the testing is being conducted and the type of diagnosis or treatment for which the devices is sold, a new authorization must be obtained from TPP. This authorization may be granted after a review of additional information related to the proposed change. This authorization must be obtained in advance of implementing the changes.

2.4 Rejection or Refusal of an Application

An investigational testing application may be rejected if the manufacturer and/or device sponsor fails to provide the records described in Section 81. The authorization may be refused if it is determined that:

- the device cannot be used safely for investigational testing;
- the investigational testing is not in the best interests of patients; or
- the objective of the testing cannot be achieved.

In the case of a refusal to issue an investigational testing authorization, the manufacturer and/or device sponsor may appeal the decision.

2.5 Additional Guidance

This guidance document, "Preparation of an Application for Investigational Testing - Medical Devices" provides information for devices in general, if a manufacturer has specific questions or concerns they are urged to contact the Manager, Device Evaluation Division, Medical Devices Bureau at (613) 954-0297.

3.0 Access to Information Act and the Confidentiality of Authorization Applications

Information provided to the Programme by manufacturers and/or device sponsors is subject to the provisions of the Access to Information Act. Authorization application information containing trade secrets, scientific, technical, commercial or financial information that is confidential is protected from disclosure by this Act. It is also the Programme's current policy to keep confidential, information regarding investigational testing authorization applications that have been received or granted.

4.0 When to Apply for an Authorization for Investigational Testing

An investigational testing application is indicated when the device has been shown to have a

reasonable probability of safety and effectiveness after the completion of all appropriate preclinical and animal studies. For some novel medical devices it is not possible to establish effectiveness unless investigational testing is carried out on humans.

5.0 Presentation of the Investigational Testing Authorization Document

Manufacturers and/or device sponsors are requested to follow the structure presented in Appendix 2 when applying for an investigational testing authorization. Sections that are not applicable should be clearly indicated. In certain instances, it may be necessary to follow a special or unique format. In such cases, the concurrence of the Manager, Device Evaluation Division should be obtained in advance.

Information in the document should be recorded in either French or English. Material in a foreign language must be accompanied by an English or French translation.

All documents should be legible and the page size, including tables should be uniform. The submission should be bound for easy access, for example in three-ring binders. Each volume must be clearly labelled and numbered both on the spine and on its front cover.

The pagination may be sequential for the entire submission or by volume. In the executive summary and table of contents, individual sections of text should be identified both by the assigned decimal number and by the correct title as suggested in Appendix 2 of this guideline document. Cross references should include both volume and page number.

6.0 The Requirements of an Application for Investigational Testing Authorization

The minimum requirements of an investigational testing authorization application are presented below. These requirements will differ depending on the risk based classification of the device in question. Readers are reminded that this guidance document is not applicable to *in vitro* diagnostic devices (refer to "Preparation of an Application for Investigational Testing - *in Vitro* Diagnostic Devices").

6.1 Class I Medical Devices

Subsection 80(3) of the *Medical Devices Regulations* permits a manufacturer or importer of a Class I medical device to sell the device to a qualified investigator for the purpose of conducting an investigational test provided the seller possesses all the records and information detailed in Section 81 of the regulations.

There is no need to make an application to the Therapeutic Products Programme to conduct investigational testing of Class I medical devices in Canada.

6.2 Class II Medical Devices

An application for an investigational testing authorization of a Class II device must contain the

following items presented in four distinct chapters titled: Introduction, Institutional Information, Protocol, and Labelling.

6.2.1 Introduction

6.2.1.1 Subsection 81(a) - Manufacturer Identification

The complete name and address of the device manufacturer and importer (if applicable) including contacts and telephone number must be provided. This information should agree with the information provided on the application form.

6.2.1.2 Subsection 81(b) - Device Identification

The manufacturer and/or device sponsor must provide the name of the device and the DEVICE IDENTIFIERS, as they appear on the label. This includes any component, part or accessory that is part of the device.

The risk classification of the device as determined by the manufacturer for the purpose of the investigational testing must be provided. This risk classification may differ from that of the device in general sale, if for example a new indication is being investigated.

6.2.2 Institutional Information

6.2.2.1 Subsection 81(h) - Name of the Institutions

For a Class II investigational testing authorization application, the name and address of each institution at which the testing is proposed to be conducted is required. These institutions will be listed as part of the Authorization provided under Subsection 83(2).

6.2.3 Protocol

6.2.3.1 Subsection 81(i) - Protocol

The protocol of the proposed investigational testing should contain the following information, in easily identifiable subsections.

- 1) The objective of the investigational testing should be presented in the form of discrete hypotheses; each hypothesis should be limited to one variable. The general study design should be described briefly, including the number of devices or patients required to achieve the testing objectives.
- 2) Detailed information should be presented on the duration of the investigation and the follow-up period for patients. Subject selection must be fully described including:
 - (i) the number of subjects, including a justification for the proposed number;
 - (ii) inclusion and exclusion criteria, including the participants' age, sex and diagnosis of primary and secondary (if applicable) conditions should be stated; and
 - (iii) the diagnostic methods chosen to confirm the disease or condition.
- 3) The methods of assessing the investigational device must be fully described,

including the criteria for success or failure of the performance of the device. This will include a copy of all case report forms to be used in the investigation. The proposed methods of data analysis should be described, including the identity of the person or group performing the analysis. Methods of data quality control should be specified.

- 4) The control group must be fully described, and a justification provided for the type of control group chosen.
- 5) Copies of the informed consent documentation must be provided. This should accurately describe the risks and benefits to the patient of participating in the proposed investigational testing.

6.2.4 Device Label

6.2.4.1 Subsection 81(j) - Device Label

Subsection 81(j) requires the manufacturer and/or device sponsor to submit a copy of the device label. This will include the product monograph and all advertising brochures intended to be used with the device. It will also include copies of information and instruction for use given to either the qualified investigator or patient.

The labelling requirements of Part 1 of the *Medical Devices Regulations* do not apply to devices authorized for sale under Part 3 of the Regulations. However there are specific labelling requirements for devices sold for investigational testing.

Section 86 of the *Medical Devices Regulations* sets out the requirements of a label on a device sold for investigational testing. In addition to the name of the device and the name of the manufacturer, two additional statements must be present. A third statement is required for IVDDs undergoing investigational testing.

Subsections 86(c) and 86(d) require that the statements “Investigational Device” and “To be Used by Qualified Investigators Only” and “Instrument de recherche” and “Réservé uniquement à l’usage de chercheurs compétents” be present in English and French. It is possible to use alternate phrasing, provided the above meanings are conveyed.

In the case of an IVDD undergoing investigational testing, Subsection 86(e) requires the statement “The performance specifications of this product have not been established” and “Les spécifications de rendement de l’instrument n’ont pas été établies” be present in English and French. An alternate phrase may be used, provided the above meaning is conveyed.

6.3 Class III and IV Medical Devices

The application for an investigational testing authorization for a Class III or IV medical device must contain the following information in six distinct chapters: Introduction; Risk Analysis; Institutional Information, Protocol, Labelling, and Investigator Agreements.

6.3.1 Introduction

6.3.1.1 Subsection 81(a) - Manufacturer Identification

The complete name and address of the device manufacturer and importer (if applicable) including contacts and telephone number must be provided. This information should agree with the information provided on the application form.

6.3.1.2 Subsection 81(b) - Device Identification

The manufacturer and/or device sponsor must provide the name of the device and the DEVICE IDENTIFIERS, as they appear on the label. This includes any component, part or accessory that is part of the device.

The risk classification of the device as determined by the manufacturer for the purpose of the investigational testing must be provided. This risk classification may differ from that of the device in general sale, if for example a new indication is being investigated.

6.3.1.3 Subsection 81(c) - Device Description

This section of the regulations requires a description of the device and of the materials used in its construction and packaging. This description should include good quality colour photographs of the device, its components, parts and accessories and engineering diagrams, where appropriate.

Engineering diagrams of long term implanted devices aid in the determination of dimensions and relative proportions. These should be provided with an original application for investigational testing. Engineering diagrams for other device types, such as electro-medical devices may be requested as ADDITIONAL INFORMATION if necessary to establish the safety and potential effectiveness of the device in question. They do not need to be provided in the original application.

A complete list of all the device components is required, including accessories and parts.

6.3.1.4 Subsection 81(d) - Design Philosophy

This paragraph requests a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented by the manufacturer. To satisfy this requirement, a brief description of the device's design philosophy and performance specifications should be provided and linked to the objectives of the proposed investigational testing. References and comparisons with appropriate previous versions or generations of the device should be presented. A tabular format is preferred for this comparison.

This section should include an overview of the purposes and principles of operation for the device and should include a summary of the method of use and operation of the

device.

6.3.1.5 Subsection 81(e) - Marketing History

In this paragraph a summary of the marketing history of the device is requested. Include a summary of special access requests made to the Programme and the outcome of these requests. In addition the manufacturer and/or device sponsor is requested to provide details of the regulatory status of the device in other major world markets, and the volume of sales to date globally. A summary of reported problems with the device and details of any recalls in other jurisdictions is also required.

6.3.2 Risk Assessment and Risk Reduction Measures

Subsection (f) Section 81 requires a risk assessment that is comprised of an analysis and evaluation of the risks inherent in the use of the device and the measures adopted to reduce these risks for the purposes of conducting the investigational testing. For further guidance in this area the reader is referred to the current draft of ISO/DIS 14971-1 "Medical Devices - risk management Part 1: Application of risk analysis".

This first element to be considered is a risk analysis. This will include the complete description and identification of the devices and accessories under consideration. A list of possible hazards must be prepared for these devices. Secondly, these risks must be evaluated against the presumed benefits of the device. And thirdly, an indication of the way by which the risks has been reduced to acceptable levels must be provided. The identity of who has carried out the risk analysis must be provided.

There are several techniques that can be used for the analysis of risk, the choice of method must be appropriate for the device and the risk involved. Different considerations and guidance are appropriate for *in vitro* diagnostic devices and devices containing materials of biological origin.

6.3.2.1 Subsection 81(f)(i) - Previous Studies

The results of any previous research, testing and studies conducted with the device must be provided. These results provide a background to the investigational testing authorization application.

6.3.2.2 Subsection 81(f)(ii) - Alternate Treatments

A description of currently available alternate treatments should be presented. This may include the methods currently used to diagnose or treat the medical conditions that are the subject of the current investigational testing authorization request.

6.3.2.3 Subsection 81(f)(iii) - Precautions

All known information respecting any cautions, warnings, contra-indications and possible adverse effects associated with the use of the device must be presented.

6.3.3 Institutional Information

6.3.3.1 Subsection 81(g) - Names of Investigators

The names of all qualified investigators to whom the device is proposed to be sold must be submitted to TPP, including their qualifications and experience. Often there are many investigators involved in an investigational test at a particular site. In this case, the principle investigator should be identified. An abbreviated *curriculum vitae*, detailing the educational qualifications of the investigator and their relevant research experience (in a related area), should be submitted.

6.3.3.2 Subsection 81(h) - Name of the Institutions

For a Class III or IV investigational testing authorization application, the name and address of each institution at which the testing is proposed to be conducted is required. These institutions will be listed as part of the Authorization provided under Subsection 80(2).

6.3.3.3 Subsection 81(h) - Research Ethics Board Approval

For Class III and IV investigational testing authorization applications, written approval from each proposed institution's Research Ethics Board must be provided with the application.

In the absence of an institutional Research Ethics Board, an Ethics Committee must be convened that conforms with the Medical Research Council Guideline on the "Code of Ethical Conduct for Research Involving Humans." This guideline is available on the MRC website at www.cihr-irsc.gc.ca or by contacting the MRC at Holland Cross, Tower B, 5th Floor, 1600 Scott Street, Postal Locator 3105A, Ottawa, Ontario K1A 0W9.

A conditional investigational testing authorization may be granted by the TPP pending the receipt of a Research Ethics Board approval. However, the investigational testing cannot begin until this approval has been obtained and submitted to the TPP.

6.3.4 Protocol

6.3.4.1 Subsection 81(i) - Protocol

The protocol of the proposed investigational testing should contain the following information, in easily identifiable subsections.

- 1) The objective of the investigational testing should be presented in the form of discrete hypotheses; each hypothesis should be limited to one variable. The general study design should be described briefly, including the number of devices or patients required to achieve the testing objectives.
- 2) Detailed information should be presented on the duration of the investigation and the follow-up period for patients. Subject selection must be fully described including:

- (i) the number of subjects, including a justification for the proposed number;
 - (ii) inclusion and exclusion criteria, including the participants' age, sex and diagnosis of primary and secondary (if applicable) conditions, should be stated; and
 - (iii) the diagnostic methods chosen to confirm the disease or condition.
- 3) The methods of assessing the investigational device must be fully described, including the criteria for success or failure of the performance of the device. This will include a copy of all case report forms to be used in the investigation. The proposed methods of data analysis should be described, including the identity of the person or group performing the analysis. Methods of data quality control should be specified.
 - 4) The control group must be fully described, and a justification provided for the type of control group chosen.
 - 5) Copies of the informed consent documentation must be provided. This should accurately describe the risks and benefits to the patient of participating the proposed investigational testing.

6.3.5 Device Label

6.3.5.1 Subsection 81(j) - Device Label

Subsection 81(j) requires the manufacturer and/or device sponsor to submit a copy of the device label. This will include the product monograph and all advertising brochures intended to be used with the device. It will also include copies of information and instruction for use given to either the qualified investigator or patient.

The labelling requirements of Part 1 of the *Medical Devices Regulations* do not apply to devices authorized for sale under Part 3 of the Regulations. However there are specific labelling requirements for devices sold for investigational testing.

Section 86 of the *Medical Devices Regulations* sets out the requirements of a label on a device sold for investigational testing. In addition to the name of the device and the name of the manufacturer, two additional statements must be present. A third statement is required for IVDDs undergoing investigational testing.

Subsections 86(c) and 86(d) require that the statements “Investigational Device” and “To be Used by Qualified Investigators Only” and “Instrument de recherche” and “Réservé uniquement à l’usage de chercheurs compétents” be present in English and French. It is possible to use alternate phrasing, provided the above meanings are conveyed.

In the case of an IVDD undergoing investigational testing, Subsection 86(e) requires the

statement “The performance specifications of this product have not been established” and “Les spécifications de rendement de l’instrument n’ont pas été établies” be present in English and French. An alternate phrase may be used, provided the above meaning is conveyed.

6.3.6 Investigator Agreements

6.3.6.1 Subsection 81(k) - Investigator Agreements

The manufacturer and/or device sponsor are required to obtain investigator agreements from each investigator enrolled in the investigational testing. This agreement outlines the responsibilities of the investigator to:

- conduct the testing in accordance with the protocol;
- fully inform each enrolled patient;
- not to permit the device to be used outside the agreed protocol;
- supervise the use of the device; and
- report all incidents under Section 59 of the regulations to the Minister within 72 hours.

A copy of an investigator agreement form is provided in Appendix 3. An alternate format is acceptable provided the five(5) conditions described in subsection 81(k) are adequately addressed.

7.0 Manufacturer and/or Device Sponsor Responsibilities

7.1 Record Keeping

The manufacturer and/or device sponsor of a medical device undergoing investigational testing in Canada, on humans must maintain the records described in Section 81 of the *Medical Devices Regulations*. For Class II, III and IV devices a portion of these records are submitted to the Therapeutic Products Programme in order to obtain the authorization detailed in Sections 82 and 83.

The requirement to maintain distribution records described in Section 52 to 56 apply to devices sold for the purpose of investigational testing.

7.2 Mandatory Problem Reporting

Sections 59 to 62 of the *Medical Devices Regulations* with respect to mandatory problem reporting apply to devices undergoing investigational testing. The investigator is responsible to notify the Therapeutic Products Programme and the manufacturer within 72 hours of any incident that meets the criteria as defined in Subsection 59(1) of the *Medical Devices Regulations*.

Subsection 59(1) defines two types of device related incidents. The first, is related to a failure or a deterioration in the effectiveness of the device or any inadequacy in its labelling or in the directions for use accompanying it. The second involves an incident that has led to the death or a

a serious deterioration in the health of a patient, user or other person or, where it is reasonable to believe that such an incident were it to recur, could lead to the death or a serious deterioration of the state of health of a patient, user or other person.

For additional information and guidance, consult the “Guidance Document for Mandatory Problem Reporting for Medical Devices” (http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2011-devices-materiaux/index-eng.php).

7.3 Other Obligations

Sections 57 and 58 and 63 to 65 of the *Medical Devices Regulations* apply to devices authorized for investigational testing. The manufacturer and/or device sponsor is required to have documented procedures in place to handle product complaints and recalls. In addition, the appropriate records of these activities must be maintained. For additional information, the guidance document "Guidance on Complaint Handling and Recall" should be consulted. This document is available on the TPP website at www.hc-sc.gc.ca/hpb-dgps/therapeut.

Sections 66 to 68 describing the manufacturers responsibilities with regard to implant registration are also applicable (as appropriate) to devices authorized for investigational testing.

Section 87 of the regulations describes the limitations placed on the advertisement of devices undergoing investigational testing in Canada. Only devices which have been authorized under subsection 83(1) can be advertised. The advertisement must clearly state the device is the subject of investigational testing and the proposed purpose of the testing.

8.0 Additional Information - Cancellation of an Authorization

Section 85 of the *Medical Devices Regulations* allows for the cancellation of an investigational testing authorization for Class II, III or IV devices and the stop sale of a Class I device for investigational purposes. The conditions for stopping an investigation test are outlined in subsection 83(1) paragraphs (a) to (e).

Prior to cancelling an authorization, TPP may request information from the manufacturer and/or device sponsor to substantiate that the conditions set out in subsection 83(1) are still applicable. If this information is not received, the authorization will be cancelled.

Appendix 1 - Application Form for Investigational Testing

(Following)



APPLICATION FOR INVESTIGATIONAL TESTING AUTHORIZATION

(disponible en français)

1. DEVICE CLASSIFICATION

- Class II
- Class III
- Class IV

2. DEVICE NAME (as it appears on label)

[Note: this is the device name for which the Authorization will be issued]

3. PROTOCOL IDENTIFICATION:

Include the type of diagnosis or treatment for which the device will be sold.

4. NAME AND ADDRESS OF MANUFACTURER (as it appears on the label)

[Note: this is the name and address to which the Authorization will be issued]

Company Name			
Street Address/P.O. Box			
City			
Province/State			
Postal/Zip Code			
Country			
Contact Name and Title:			
Telephone No.:		Fax No.:	
E-Mail Address:			



APPLICATION FOR INVESTIGATIONAL TESTING AUTHORIZATION

(disponible en français)

5. MAILING ADDRESS FOR REGULATORY CORRESPONDENCE (if different from 4)

Note: (i) The authorization will be issued to Company named in Item 4 but will be sent to the Company shown below if different. (ii) The Company named below must be authorized by the manufacturer named in Item 4 to submit an authorization application on their behalf. See the Authorization of Contact form for details.

Company Name:	
Street Address/P.O. Box	
City	
Province/State	
Postal/Zip Code	
Country	
Contact Name and Title:	
Telephone No.:	Fax No.:
E-Mail Address:	

6. DEVICE TYPE (check one only)

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

7. PREFERRED NAME CODE: (xxAAA) optional

--

8. IS THIS DEVICE A NEAR PATIENT *IN VITRO* DIAGNOSTIC (IVDD)? Yes No

IS THIS DEVICE INTENDED TO BE SOLD FOR HOME USE Yes No



APPLICATION FOR INVESTIGATIONAL TESTING AUTHORIZATION

(disponible en français)

9. DEVICE USAGE CATEGORY

(73) Anaesthesiology	
(74) Cardiovascular	
(76) Dental	
(77) Ear, Nose & Throat	
(78) Gastroenterology & Urology	
(79) General & Plastic Surgery	
(80) General Hospital	

(84) Neurology	
(85) Obstetrics & Gynaecology	
(86) Ophthalmology	
(87) Orthopaedics	
(89) Physical Medicine	
(90) Radiology/Imaging	

FOR IVDDs ONLY

(75) Chemistry	
(81) Haematology	
(82) Immunology	

(83) Microbiology	
(88) Pathology	
(91) Clinical Toxicology	

10. DOES THIS DEVICE CONTAIN A DRUG?

Yes No

(Note: this question does not apply to IVDDs)

If yes

Brand /Trade Name of Drug:
Active Ingredient:
Drug Manufacturer:
Applicable Drug Identification Number (if any):



APPLICATION FOR INVESTIGATIONAL TESTING AUTHORIZATION

(disponible en français)

12. ATTACHMENTS

In addition to items 1 to 11, of the Application for investigational testing, please indicate (✓) which of the relevant information requirements listed below, are included as attachments to this application, or will be provided at a later date. For details regarding content and format, please refer to the guidance documents "Preparation of an Application for Investigational Testing - Medical Devices" and "Preparation of an Application for Investigational Testing - in Vitro Diagnostic Devices"

	Attached	To Come
Background Information		
Risk Assessment		
Ethics Committee or IRB Approval(s)		
Protocol		
Device Label		
Investigator Agreements		

13. If this Device contains a drug and it does **not** have a Drug Identification Number, **I the Manufacturer of this device attest** that the (**drug meets**) (**drug does not meet**) acceptable standards of safety, efficacy and quality.

I hereby certify that the information provided on this application and in any attached documentation is correct, complete and in accordance with all relevant sections of the *Medical Devices Regulations*.

Name of Signing Official: _____

Signed: _____ Date: _____



AUTHORIZATION OF CONTACT

(disponible en français)

(application type)

This form authorizes the person named in **Section B** to submit this application for : a new device licence; an amended device licence; investigational testing; on behalf of the company identified in **Section A**.

Section A

I hereby authorize the person named in **Section B** to submit this application for: a new device licence; an amended device licence; investigational testing; to the Minister on my behalf. The Medical Devices Bureau will accept either this form or a signed letter of authorization on company letterhead.

Name: _____

Title: _____

Company: _____

Telephone Number: _____ Fax Number: _____

Signature: _____ Date: _____

Section B

I hereby accept the responsibility to submit this application for: a new device licence; an amended device licence; investigational testing; to the Minister by the person named in **Section A**. The Medical Devices Bureau will accept either this form or a signed letter of authorization on company letterhead.

Name: _____

Title: _____

Company: _____

Telephone Number: _____ Fax Number: _____

Signature: _____ Date: _____

Medical Devices Bureau
Room 1605, Statistics Canada Main Building
Tunney's Pasture, Address Locator: 0301H1
Ottawa, Ontario
K1A 0L2

Appendix 2 - Proposed Format for an Investigational Testing Application

The following is the suggested format for an investigational testing application, some of the sections are not applicable to Class II applications.

Application Form
Executive Summary
Table of Contents
1 Background Information
1.1 Device Description
1.2 Design Philosophy
1.3 Marketing History
2 Risk Assessment
2.1 Risk Analysis and Evaluation
2.2 Previous Studies
2.3 Alternate Treatments
2.4 Precautions
3 Institutional Information
3.1 Investigator(s)
3.2 Name of Institution(s)
3.3 Research Ethics Board Approval(s)
4 Protocol
5 Device Label
6 Investigator Agreement(s)

APPENDIX 3 - INVESTIGATOR'S AGREEMENT

INVESTIGATOR'S AGREEMENT IN ACCORDANCE WITH SUBSECTION 81(k) OF THE *MEDICAL DEVICES REGULATIONS*

Device Name/Nom de l'instrument: _____

Protocol Number/N° du Protocole: _____

I, _____, undertake,
as outlined in Subsection 81(k) of the *Medical
Devices Regulations*, to:

(i) conduct the investigational testing in accordance
with the protocol:

(ii) inform a patient who is to be diagnosed or treated
with the device of the risks and benefits associated
with its use and obtain the written consent of the
patient,

(iii) not use the device or permit it to be used for any
purpose other than the investigational testing
specified in the protocol,

(iv) not permit the device to be used by any person
other than myself, except under my direction,

(v) in the event of an incident that is related to a
failure of the device or a deterioration in its
effectiveness, or any inadequacy in its labelling or in
its directions for use and has lead to the death or a
serious deterioration in the state of health of a patient,
user or other person, or could do so were it to recur,
report the incident and the circumstances surrounding
it to the Director and the manufacturer or importer of
the device, within 72 hours after its discovery.
(Tel: (613) 954-6666 Fax: (613) 954-0941)

Je, _____, m'engage
conformément à la section 81(k) du *Règlement sur les
instruments médicaux*, comme décrits ci-bas, à :

(i) effectuer l'essai expérimental conformément au
protocole:

(ii) informer le patient qui fera l'objet du diagnostic
ou du traitement au moyen de l'instrument des risques
et des avantages que comporte son utilisation et
obtiendra son consentement écrit,

(iii) ne pas utiliser l'instrument ni n'en permettre
l'utilisation à des fins autres que l'essai expérimental
décrit dans le protocole,

(iv) ne pas permettra que l'instrument soit utilisé par
une personne autre que moi, sauf sous ma direction,

v) advenant un incident qui d'une part, est lié à une
défaillance de l'instrument, une dégradation de son
efficacité ou un étiquetage ou mode d'emploi
défectueux; d'autre part a entraîné la mort ou une
détérioration grave de l'état de santé d'un patient,
utilisateur ou autre personne, ou serait susceptible de
le faire s'il se reproduisait, rapporter l'incident en
question de même que les circonstances s'y
rattachant, au Directeur et au fabricant, ou à
l'importateur de l'instrument, et ce, en deçà de 72
heures après la découverte de l'incident.
(Tél: (613) 954-6666 Téléc. : (613) 954-0941)

Signature

Date