

Please complete this application in its entirety, as the responses given are material to the provision of terms. There is space for more details in the Additional Information Section at the end of the application. Coverage may be provided on a claims-made basis.

Named Insured: _____
 Street Address: _____
 City: _____ Province: _____ Postal Code: _____
 Contact: _____ Email: _____ Phone: _____

Section 1: About Your Organization

1. What year was your organization established: _____
2. Is your organization incorporated? Yes No
3. Do you expect a material change in your operations in the next 12 months? If Yes, please provide details.* Yes No
4. Have you operated under another name? If Yes, please provide details.* Yes No
5. Have you acquired any subsidiaries in the past 5 years? If Yes, please provide details.* Yes No
6. Have you filed for bankruptcy in the past 10 years? If Yes, please provide details.* Yes No
7. Has your organization, or any shareholders, directors, officers, partners, or members thereof, been under any investigation for alleged criminal violations relating to your business? If Yes, please provide details.* Yes No
8. Please list any additional locations not noted above:

Street Address: _____
 City: _____ Province: _____ Postal Code: _____
 Street Address: _____
 City: _____ Province: _____ Postal Code: _____

9. Please list any of your subsidiaries or related entities that are controlled by or control your organization:

Entity Name	Description of Operations	Relationship to Named Insured

10. Please describe all of your operations: _____

Section 2: Revenues

1. Please indicate your gross revenue by the following breakdown:

	Revenue: Previous 12 Months			Forecasted Revenue: Next 12 Months		
	Canada	U.S.A.	Rest of World	Canada	U.S.A.	Rest of World
Manufacturing and Sale of Own Product						
Manufacturing is Contracted Out for Own Product						
Contract Manufacturing for Third Parties						
Wholesale/Distribution of Third Party's Products						
Repackaging or Relabelling of Wholesale Products						
Retail Sales						
Licensing Agreements, Royalties						
Research & Development, Milestones						
Consulting for a Fee						
Other:						

2. Please indicate the countries outside of Canada and the United States of America where you have sales/revenues:

* Please provide further details in the space provided under the Additional Information Section.

Section 3: Premises

1. Please indicate your organization’s biohazard laboratory rating:
2. Do you store hazardous materials at your premises? If Yes, please provide details.* Yes No
3. Do you store and dispose of all hazardous materials in compliance with federal and provincial laws and regulations? Yes No
4. Do you have any laboratory animals on premises? Yes No
5. Do you have any personal property of others in your care, custody or control? If Yes, please provide details.* Yes No

Section 4: Your Products

1. Please list your 10 top-selling products by approximate percentage (%) of gross revenue:

%	Your Product				

2. Please indicate your sales by Class of medical device by approximate percentage (%) of gross revenue:

Class I	Class II	Class III
Class IV	Custom Made Device	

3. Please indicate your sales by type of medical device by percentage (%) of total gross revenue:

Analytical Instruments	Drug Delivery	Monitoring Devices
Anaesthesia, Respiratory	Hospital Products, Supplies	Mobility Aides
Cardiovascular	Imaging Devices	Surgical Devices
Dental Instruments	Implantable: Active	Surgical Instruments
Diagnostic Devices	Implantable: Non-Active	Therapeutic Devices
Dialysis	Lasers	Other - please specify below:

4. Have any of your products been on the market for less than 3 years? If Yes, please provide details.* Yes No
5. Have any of your products been recalled or withdrawn in the past 5 years? If Yes, please provide details.* Yes No
6. Have any Adverse Event Reports been filed on any of your products in the past 5 years? Yes No
7. If Yes to 6., was your product associated with death, hospitalisation, or permanent injury? Yes No
8. Are any of your products sold under third-party labels or as a component(s) of others’ products? If Yes, please provide details.* Yes No
9. Do you and your suppliers use Canadian-approved chemicals and ingredients as per Controlled Drugs and Substances Act, Canadian Food and Drug Act, and Natural Health Products Regulations? Yes No
10. Are all of the products you sell approved by Health Canada, the Federal Drug Agency, and/or the relevant local governing body? Yes No
11. Do you intend to bring any new product(s) to market in the next 12 months? If Yes, please provide details.* Yes No
12. Do you provide any type of clinical services as part of your operations? If Yes, please provide details.* Yes No
13. Do any of your staff interact directly with end users/consumers? If Yes, please provide details.* Yes No

* Please provide further details in the space provided under the Additional Information Section.

Section 5: Specific Products

1. Please indicate if you are involved with any of the following **products or their derivatives**. Please note that some of the products below may be excluded in the insurance policy, but coverage could be extended in some circumstances: Yes No

Animal Derived	Human Derived	IVC Filters	Pain Pumps
Breast Implants	Implantable Mesh	Latex Condoms	Pedicle Screws
Contains Gel or Liquid Silicone	Insulin Pumps	Latex Gloves	Wheelchairs (incl. Powered)
Contains Mercury	IUDs	Metal-on-Metal Joints	

Section 6: Regulatory and Risk Management

- 1. Are you in compliance with all applicable regulatory guidelines? Yes No
- 2. Have you been cited for any regulatory violations in the past 5 years? If Yes, please provide details.* Yes No
- 3. Do you follow Good Manufacturing Practices (GMP)? Yes No
- 4. Are you ISO registered? If Yes, please provide ISO number: _____
- 5. For how many years do you maintain batch samples of your products? _____
- 6. Do you conduct regular batch testing (including alcohol % for hand sanitizer)? Yes No
- 7. Do you have a formal Product Recall Procedure in place? Yes No
- 8. Do you have a formal written Quality Control and/or Quality Assurance program(s) in place? Yes No
- 9. Do you maintain all rights of recourse against your suppliers and/or product manufacturers? Yes No
- 10. Do you have a Risk Management and Loss Prevention Program in place? Yes No
- 11. Please provide your current Pharmaceutical Product Establishment License: _____
- 12. Please indicate the last date of inspection by Health Canada. _____
- 13. Do you have procedures for documenting incident reports or complaints? Yes No
- 14. Do you obtain a certificate of insurance from all suppliers and contractors? Yes No
- 15. Are all contracts reviewed by Legal or your legal representative? Yes No
- 16. Do you review all policies and procedures on a regular and ongoing basis? Yes No

Section 7: Claims History

- 1. Have you ever had a claim against your organisation’s insurance policies? If Yes, please provide details including date of loss, amount paid or held in reserve, and description of allegation.* Yes No
- 2. Are you aware of any incidents or circumstances that could potentially give rise to a claim? If Yes, please provide details.* Yes No

Section 8: Prior Insurance

1. Have you ever been declined coverage, cancelled or non-renewed for insurance requested in this application? Yes No

2. Please provide details of your expiring insurance policy:

Coverage	Insurer	Limit	Aggregate	Deductible	Retroactive Date	Premium
General Liability						
Product Liability						
Errors & Omissions						
Medical Malpractice						
Product Recall						
Products: Clinical Trials						

* Please provide further details in the space provided under the Additional Information Section.

Section 9: Requested Insurance Coverage

1. Please indicate the coverage limit, aggregate, retroactive date, and deductible you are requesting:

Coverage	Limit	Aggregate	Deductible	Retroactive Date
General Liability				
Product Liability				
Errors & Omissions				
Medical Malpractice				
Product Recall				
Products: Clinical Trials				

Privacy Policy

By signing this form, you are consenting to the collection, use, disclosure, and retention of your personal information for the purposes of underwriting and rating, policy issuance, processing and remitting premium, reporting claims, complying with applicable laws and governing bodies, reporting and monitoring results and fraud and criminal prevention. Please see www.signalunderwriting.com/privacy-statement for our External Privacy Policy.

Declarations

I/We, the undersigned, do declare and warrant that all statements and responses provided in this application and the attached addenda are to the best of my/our knowledge are true. Further, I/we warrant that no information has been withheld, suppressed or misstated any material facts that the underwriters may come to rely upon. I/We will notify the underwriters as soon as practicable if anything material is to change. I/We hereby agree and accept that this Declaration shall be the basis of such contract and will form part of the policy. Signing this application does not bind the underwriters or insurers to complete the insurance, nor does it bind me/us to purchase the quoted coverage.

For British Columbia residents: Signal Underwriting Inc. operates as Signal Underwriting Services in British Columbia.

For Quebec and New Brunswick residents: Signing this Declaration confirms your request that all documentation and correspondence pertaining to the insurance coverage be in the English language.

Name (please print)	Title	Date

Signature

* Please provide further details in the space provided under the Additional Information Section.

Medical Devices Application Addenda

Please complete the relevant section(s) to your operations.

Addendum: Contract Manufacturing

1. Do you always use standard contracts prior to providing services (including change orders)? Yes No
2. What is the average dollar value of your contracts? _____
3. What is the average duration of your contracts? _____
4. What is the total number of your current contracts? _____
5. Have any of your clients ceased payment or requested a refund of fees in the past 3 years? If Yes, please provide details.* Yes No
6. Please indicate your largest 3 contracts for the current year:

Type of Customer	Contract Value	Services Provided

Addendum: Clinical Trials

1. Please complete this schedule of the current human clinical trials you are involved with:

Product/Protocol Name and Number	Phase	No. of Subjects		Country	Indication/ Disease Tested	Status	Revenue (If Any)
		Current	Total				

2. Are all trials conducted in accordance and registered with appropriate local government authorities? Yes No
3. Are all trials conducted in accordance with Ethics Committee/Research Ethics Board approval? Yes No
4. Are all trials conducted in accordance with I.C.H. guidelines? Yes No
5. Do you recruit your own subjects? Yes No
6. Does the clinical trial include clear informed consent for all potential participants? Yes No
7. Do you give medical advice or operate an inpatient facility as part of the clinical trial? Yes No
8. Have any Adverse Event Reports been filed on any of your products in the past 5 years? Yes No
9. If Yes to 8., was your product associated with death, hospitalisation, or permanent injury? Yes No
10. Please provide the number of Expanded Access/Compassionate Use participants: _____
11. Have any Clinical Investigators been cited for regulatory violations in connection with you? Yes No
12. Do your clinical trials involve any of the following: minors, infants, women that are known to be pregnant, birth control, genetic engineering, gene therapy, withdrawn pharmaceuticals, opioids, cannabis, an invasive practice or ethical implications? Yes No
13. Do you assume liability under contract for the product? Yes No
14. Does the contract have hold harmless agreements in place in the favour of your organization? Yes No
15. Did a member of staff or physician practicing at your facility write the clinical trial protocols? Yes No
16. Is the presiding physician a member of the CMPA? Yes No

* Please provide further details in the space provided under the Additional Information Section.