Medical Devices Application

SIGNAL UNDERWRITING

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 O No O

3. Do you expect a material change in your operations in the next 12 months? If Yes, please provide details.* Yes O No O

4. Have you operated under another name? If Yes, please provide details.* Yes O No O

5. Have you acquired any subsidiaries in the past 5 years? If Yes, please provide details.* Yes O No O

6. Have you filed for bankruptcy in the past 10 years? If Yes, please provide details.* Yes O No O

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 O No O

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 O No O
3. Do you store and dispose of all hazardous materials in compliance with federal and provincial laws and regulations? Yes O No O
4. Do you have any laboratory animals on premises? Yes O No O
5. Do you have any personal property of others in your care, custody or control? If Yes, please provide details.* Yes O No O

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 O No O
5. Have any of your products been recalled or withdrawn in the past 5 years? If Yes, please provide details.* Yes O No O
6. Have any Adverse Event Reports been filed on any of your products in the past 5 years? Yes O No O
7. If Yes to 6., was your product associated with death, hospitalisation, or permanent injury? Yes O No O
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 O No O
9. Are all of the products you sell approved by Health Canada, the Federal Drug Agency, and/or the relevant local governing body? Yes O No O
10. Do you intend to bring any new product(s) to market in the next 12 months? If Yes, please provide details.* Yes O No O
11. Do you provide any type of clinical services as part of your operations? If Yes, please provide details.* Yes O No O
12. Do any of your staff interact directly with end users/consumers? If Yes, please provide details.* Yes O No O

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 O No O

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

2. If you have indicated Yes to 1., please indicate what product(s) or their derivative(s) are included in your products:

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

Section 6: Regulatory and Risk Management

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

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 O	No O
2. Are you aware of any incidents or circumstances that could potentially give rise to a claim? If Yes, please provide details.*	Yes O	No O

Section 8: Prior Insurance

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

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						
Clinical Trial Liability						

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				
Clinical Trials Liability				

2. Confirm coverage has been in place continuously from Retroactive Dates requested?	Yes O	No O

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

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

Additonal Information Section

Please use this space to provide any additional information from the questions above, from the addenda or anything you feel is material to your operations:

* 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

7. 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				

8. Are all trials conducted in accordance and registered with appropriate local government authorities? Yes ☐ No ☐
9. Are all trials conducted in accordance with Ethics Committee/Research Ethics Board approval? Yes ☐ No ☐
10. Are all trials conducted in accordance with I.C.H. guidelines? Yes ☐ No ☐
11. Do you recruit your own subjects? Yes ☐ No ☐
12. Does the clinical trial include clear informed consent for all potential participants? Yes ☐ No ☐
13. Do you give medical advice or operate an inpatient facility as part of the clinical trial? Yes ☐ No ☐
14. Have any Adverse Event Reports been filed on any of your products in the past 5 years? Yes ☐ No ☐
15. If Yes to 8., was your product associated with death, hospitalisation, or permanent injury? Yes ☐ No ☐
16. Please provide the number of Expanded Access/Compassionate Use participants: _____
17. Have any Clinical Investigators been cited for regulatory violations in connection with you? Yes ☐ No ☐
18. 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 ☐
19. Do you assume liability under contract for the product? Yes ☐ No ☐
20. Does the contract have hold harmless agreements in place in the favour of your organization? Yes ☐ No ☐
21. Did a member of staff or physician practicing at your facility write the clinical trial protocols? Yes ☐ No ☐
22. Is the presiding physician a member of the CMPA? Yes ☐ No ☐

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