



## MEDICAL DEVICE LIABILITY INSURANCE APPLICATION

THIS APPLICATION IS FOR A CLAIMS MADE POLICY

**PLEASE ENSURE THAT THE FOLLOWING ARE PROVIDED WITH THE APPLICATION**

- Company brochures (if different than website product description)
- Product catalogue
- Curriculum vitae of key personnel
- Copies of all applicable contracts (i.e. development agreements, service agreements, license agreements, etc.)

### 1. GENERAL INFORMATION

1. Name of Organization or Legal Entity (Company) including any subsidiaries :

\_\_\_\_\_ (please show complete as you wish it to appear on the policy)

2. Address (Not P.O. Box):

\_\_\_\_\_

Website: \_\_\_\_\_

3. Branch Offices (if any):

\_\_\_\_\_

4. Parent Company: \_\_\_\_\_

5. Limit of Liability requested:  \$1,000,000  \$2,000,000  Other :\$ \_\_\_\_\_

### 2. COMPANY INFORMATION

6. Date established: \_\_\_\_\_

7. Fully describe your Company's operations: \_\_\_\_\_

8. 1) Gross Revenues for the last twelve (12) months or last fiscal year (\$CDN):  
 CANADA \$ \_\_\_\_\_ U.S. \$ \_\_\_\_\_ OTHER (please list countries): \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_

2) Estimated Gross Revenues for the next twelve (12) months or next fiscal year (\$CDN):  
 CANADA \$ \_\_\_\_\_ U.S. \$ \_\_\_\_\_ OTHER (please list countries): \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_

**MEDICAL DEVICE LIABILITY INSURANCE APPLICATION**

9. 1) Your Company has/will be engaged in:

OPERATIONS	LAST TWELVE (12) MONTHS			NEXT TWELVE (12) MONTHS		
	CANADA	U.S.	OTHER	CANADA	U.S.	OTHER
Manufacturing:						
Distributing:						
Retailing (direct to public)						
Research (for others):						
Other (please specify):						
TOTAL (total figures in D1) must equal totals figures in D 2))						

2) Please provide a breakdown of your revenues by class of device (as defined by Health Canada, the FDA in the U.S., or any other regulatory authority).

	LAST TWELVE (12) MONTHS			NEXT TWELVE (12) MONTHS		
	CANADA	U.S.	OTHER	CANADA	U.S.	OTHER
Class 1:						
Class 2:						
Class 3:						
Class 4:						
Other:						
TOTAL (total figures in D2) must equal totals figures in D1))						

**3. PRODUCT INFORMATION**

10. Please list your Company's products and indicate whether you are the manufacturer or distributor. If you are the manufacturer, please indicate whether you manufacture the entire product or only a part of it. For distributed products, please indicate the product's country of origin.

PRODUCT	% OF TOTAL REVENUE	MANUFACTURER OR DISTRIBUTOR	WHOLE OR PART	COUNTRY OF ORIGIN (for distribution only)

(Attach list if necessary)

11. Are any products manufactured or sold under others' labels?  YES  NO  
If YES, please also complete the attached CONTRACTOR MANUFACTURERS' LIABILITY ADDENDUM.

12. Does your Company plan to introduce any new product(s) and/or service(s) within the next twelve (12) months?  YES  NO  
If YES, please list and describe: \_\_\_\_\_

13. Are any of your Company's products required to be sold sterile?  YES  NO  
If YES, please indicate if your Company or a third party sterilizes the product. Please identify the third party: \_\_\_\_\_

Is your Company being held harmless in those instances where the product sterilization has been subcontracted out?  YES  NO  
If NO, why not? \_\_\_\_\_

14. Have any of your Company's products for any reason been recalled, discontinued or withdrawn from the market?  YES  NO  
If YES, please provide full details including the date, products involved, reason for the recall, discontinuation or withdrawal and the outcome (use separate sheet if necessary):  
\_\_\_\_\_  
\_\_\_\_\_

## MEDICAL DEVICE LIABILITY INSURANCE APPLICATION

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15. Have any of your Company's products ever been subject to an inquiry or been investigated by any regulatory authority?  YES  NO  
If YES, please provide full details including the date, products involved, reason for the investigation or inquiry and the outcome (use separate sheet if necessary):  
\_\_\_\_\_  
\_\_\_\_\_
16. Does your Company provide training on the use and maintenance of its product(s)?  YES  NO  
If YES, please advise qualifications of Company employees responsible for these matters:  
\_\_\_\_\_  
\_\_\_\_\_
17. Does your Company provide maintenance and/or repair services for its customers?  YES  NO  
If YES, what is the annual revenue derived from this source (in \$CDN)? \$ \_\_\_\_\_
18. Please describe the nature of the maintenance and/or repair services.  
\_\_\_\_\_  
\_\_\_\_\_
19. Does your Company subcontract these services to others?  YES  NO  
If YES, please provide a copy of the contract for our review.
20. Are you added to the subcontractor's policy as an additional insured?  YES  NO

### 4. RISK MANAGEMENT PRACTICES

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21. Is your Company currently in compliance with all applicable government regulations?  YES  NO  
If NO, please provide a copy of the compliance report and all applicable correspondence.  
When will your Company be in compliance? \_\_\_\_\_
22. Does your Company have a written quality control program?  YES  NO  
If YES, please advise the most recent revision date: \_\_\_\_\_  
If NO, when will one be in place? \_\_\_\_\_
23. Does your Company have a formal product recall program in place?  YES  NO  
If YES, please advise the most recent revision date: \_\_\_\_\_  
If NO, when will one be in place? \_\_\_\_\_
24. Does your Company maintain a written record of incident reports and/or complaints?  YES  NO  
If YES, who in your Company is responsible for these matters? \_\_\_\_\_  
If NO, why are written records not kept? \_\_\_\_\_
25. Does your Company follow Good Manufacturing Practices (GMP)?  YES  NO  
Are you ISO registered?  YES  NO  
If YES, what level? \_\_\_\_\_
26. Does your Company maintain samples of its product(s)?  YES  NO  
If YES, for how long are they retained? \_\_\_\_\_  
Who in your Company is responsible to maintain these samples? \_\_\_\_\_
27. Are any materials or products handled by your Company hazardous, either by themselves or in combination with other materials?  YES  NO  
If YES, please advise which materials/products and how they are contained:  
\_\_\_\_\_  
\_\_\_\_\_
28. Does your Company keep laboratory animals on the premises?  YES  NO  
If YES, please indicate the type of animals, the number and purpose.

ANIMAL	NUMBER	PURPOSE

29. Does your Company consult with legal counsel for issues concerning the following:

- |                       |                              |                             |   |
|-----------------------|------------------------------|-----------------------------|---|
| Contractual Liability | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |
| Product Labeling      | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |
| Product Instructions  | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |
| Product Guarantees    | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |
| Promotional Materials | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |
| Instruction Manuals   | <input type="checkbox"/> YES | <input type="checkbox"/> NO | <input type="checkbox"/> Not Applicable |

**5. CLINICAL TRIALS \*For each clinical trial a copy of the Protocol and the Informed Consent must be attached.**

30. Does your Company require coverage for Clinical Trials?  YES  NO  
 If YES, please complete a CLINICAL TRIAL ADDENDUM for each trial.  
 If NO, please proceed to Section 6 (PREVIOUS INSURANCE).

31. Has the proposed clinical trial(s) been approved by the appropriate government authorities?  YES  NO  
 If NO, please provide details :  
 \_\_\_\_\_  
 \_\_\_\_\_

32. Are all trial participants required to sign an informed consent form?  YES  NO  
 If NO, please explain:  
 \_\_\_\_\_  
 \_\_\_\_\_

33. Will your Company be conducting the clinical trial(s)?  YES  NO  
 If NO, please identify who has been contracted to conduct the trial(s) on your Company's behalf and provide details of any hold harmless/indemnification agreements:  
 \_\_\_\_\_  
 \_\_\_\_\_

34. Who will be the principal investigators in the clinical trial(s)?  
 \_\_\_\_\_  
 \_\_\_\_\_

35. Do any of your Company's researchers own or have stock in the Company?  YES  NO  
 If YES, please list and advise percentage (%) of ownership:  
 \_\_\_\_\_  
 \_\_\_\_\_

36. Within the next twelve (12) months, is your Company planning to manufacture any product(s) currently under investigation?  YES  NO  
 If YES, please list and provide details:  
 \_\_\_\_\_  
 \_\_\_\_\_

37. Within the next twelve (12) months, does your Company plan to sell any of its research conclusions to others?  YES  NO  
 If YES, please provide details:  
 \_\_\_\_\_  
 \_\_\_\_\_

# CLINICAL TRIAL ADDENDUM

(Please complete a separate Addendum for each trial)

Protocol Title: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

Trial Phase: Phase I:  Phase II:  Phase III:  Phase IV:  OTHER: \_\_\_\_\_

Number of sites: CANADA: \_\_\_\_\_ U.S.: \_\_\_\_\_ OTHER: \_\_\_\_\_  
(for OTHER, please list all countries)

Number of subjects: CANADA: \_\_\_\_\_ U.S.: \_\_\_\_\_ OTHER: \_\_\_\_\_

Please indicate the anticipated number of patients to be enrolled/dosed in the next twelve (12) months:  
CANADA: \_\_\_\_\_ U.S.: \_\_\_\_\_ OTHER: \_\_\_\_\_

What date will you begin enrolling patients? \_\_\_\_\_

What date will you begin dosing patients? \_\_\_\_\_

What is the duration of a patient’s participation? \_\_\_\_\_

What is the expected completion date of this trial? \_\_\_\_\_

Please describe the purpose of this clinical investigation: \_\_\_\_\_

Please list known side effects of this product: \_\_\_\_\_

Please provide a copy of the final testing, protocol, informed consent forms, any hold harmless/indemnification agreements.

## 6. CONTRACT MANUFACTURERS’ ADDENDUM (If not performing any contract manufacturing services, proceed to Section 7 – PREVIOUS INSURANCE)

With respect to the product(s) your Company is manufacturing for others, please answer the following questions:

38. Please indicate the percentage (%) of products made to the specifications of others: \_\_\_\_\_ %

39. Please indicate the percentage (%) of products made to your Company’s own specifications: \_\_\_\_\_ %

40. Does your Company manufacture and/or assemble the final product(s)?  YES  NO  
If NO, please explain: \_\_\_\_\_

41. Does your Company require signed final acceptance from its customers?  YES  NO  
If NO, please explain: \_\_\_\_\_

42. Which of the following services does your Company provide:

- Research and development:  YES  NO
- Regulatory consulting:  YES  NO
- In-house design and prototyping:  YES  NO
- Engineering:  YES  NO
- Product labeling:  YES  NO
- Packaging validation:  YES  NO
- Material supply and management:  YES  NO
- Inventory management:  YES  NO
- Warehousing:  YES  NO
- End-user shipping:  YES  NO
- Logistics management:  YES  NO
- Sales and marketing:  YES  NO
- Other (please specify): \_\_\_\_\_  YES  NO

**MEDICAL DEVICE LIABILITY INSURANCE APPLICATION**

43. Please list your Company's five (5) largest customers and provide a description of services being offered including the total revenue derived from each:

CUSTOMER NAME	DESCRIPTION OF SERVICES	TOTAL REVENUE
1)		
2)		
3)		
4)		
5)		

With Products Manufactured on behalf of a Third Party, does the Third Party company provide the following?

- Product Labels(s):  YES  NO
- Product Packaging:  YES  NO
- Product Instruction Manuals:  YES  NO
- Product Promotional Materials:  YES  NO
- Product Warranty:  YES  NO
- Packaging Training (if applicable):  YES  NO
- Products Maintenance/Repair:  YES  NO

**7. PREVIOUS INSURANCE**

44. Is your Company currently insured under a Products Liability policy?  YES  NO  
 If YES, please complete the following:

Insurer: \_\_\_\_\_ Policy Period: \_\_\_\_\_  
 Policy Number: \_\_\_\_\_ Limit of Liability: \_\_\_\_\_

45. During the last five (5) years, has your Company carried Products Liability insurance?  YES  NO  
 If YES, please complete the following for all previous Products Liability policies:

INSURER	TERM	LIMIT	DEDUCTIBLE	PREMIUM	OCCURRENCE OR CLAIMS MADE	RETRO DATE

46. Has your Company, its partners, directors or officers ever been declined, non-renewed or cancelled by any Insurer for Products Liability insurance?  YES  NO  
 If YES, please explain:

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**8. CLAIMS INFORMATION**

47. Has your Company, its partners, directors, officers or employees ever had a written demand or civil proceedings for compensatory damages made against them during the last five (5) years?  YES  NO  
 If YES, please provide the following details on a separate sheet:

- 1) Date of claim
- 2) Claimant's name
- 3) Nature of claim
- 4) Amount of indemnity payment and amount of defense costs
- 5) Final dispositions or current status of claim

**MEDICAL DEVICE LIABILITY INSURANCE APPLICATION**

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48. Is your Company, its partners, directors, officers or employees aware of any job disputes or fee disputes during the last ten (10) years?  YES  NO

If YES, please describe in detail:

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49. Is your Company, its partners, directors, officers or employees aware of any other fact, situation or circumstance, that may result in a written demand or civil proceeding for compensatory damages?  YES  NO

If YES, please describe in detail:

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Without limitation of any other remedy available to the Insurer, it is hereby agreed that if there be knowledge of any of the matters described above, any written demand or civil proceedings for compensatory damages subsequently emanating therefrom is excluded from coverage under the proposed insurance.

**9. NOTICE CONCERNING PERSONAL INFORMATION**

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By purchasing insurance from Beazley Canada Limited, a customer provides Beazley with his or her consent to the collection, use and disclosure of personal information, including that previously collected, for the following purposes:

- the communication with underwriters;
- the underwriting of policies;
- the evaluation of claims;
- the detection and prevention of fraud;
- the analysis of business results;
- purposes required or authorized by law.

For the purposes identified above, personal information may be disclosed to Beazley's and related or affiliated companies and service providers.

Further information about Beazley's personal information protection policy may be obtained by contacting their privacy officer at 416-601-2155.

**10. WARRANTY STATEMENT**

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The undersigned warrants that to the best of his or her knowledge, the statements set forth in this Application are true. The undersigned also warrants that they have not suppressed or misstated any material facts.

If the information provided in this Application should change between the date of the Application and the effective date of the policy, the undersigned warrants he or she will immediately report such changes to the Insurer.

Signing of this Application does not bind the undersigned to purchase this insurance, nor does it bind the Insurer to complete this insurance. However, should the Insurer bind and issue a policy, this Application shall serve as the basis of such contract and will be attached to, and form part of, the policy.

SIGNED: \_\_\_\_\_ DATE: \_\_\_\_\_  
(Authorized Representative)

NAME: (Please Print) \_\_\_\_\_ TITLE/POSITION: \_\_\_\_\_