

MEDICAL DEVICE LIABILITY INSURANCE APPLICATION

THIS APPLICATION IS FOR A CLAIMS MADE POLICY.

FOR PURPOSES OF THE *INSURANCE COMPANIES ACT (CANADA)*, THIS DOCUMENT WAS ISSUED IN THE COURSE OF LLOYD'S UNDERWRITERS' INSURANCE BUSINESS IN CANADA.

ALL QUESTIONS MUST BE ANSWERED COMPLETELY. DO NOT LEAVE ANY SPACE BLANK. INDICATE "N/A" IF A QUESTION IS NOT APPLICABLE. IF THE SPACE PROVIDED IS INSUFFICIENT TO ANSWER A QUESTION FULLY, PLEASE ATTACH DETAILS ON A SEPARATE SHEET.

PLEASE ENSURE THAT THE FOLLOWING ARE PROVIDED WITH THE APPLICATION:

- Company brochures (if different than web site 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

- A) Name of your Company: _____

 (Please show complete name as you wish it to appear on the policy)
- B) Mailing Address: _____

- C) Web Site Address: _____
- D) Branch Offices (if any): _____
- E) Parent Company: _____
- F) Limit of Liability requested: \$1,000,000 \$2,000,000 Other \$ _____

2. COMPANY INFORMATION

- A) Year established: _____
- B) Fully describe your Company's operations: _____
- C) 1) Gross Revenues for the last twelve (12) months or last fiscal year (\$CDN):
- | | | | |
|-----------------|---------------|--------------------------------------|----------|
| CANADA \$ _____ | U.S. \$ _____ | OTHER (please list countries): _____ | \$ _____ |
| | | | \$ _____ |
| | | | \$ _____ |
| | | | \$ _____ |

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2) Estimated Gross Revenues for the next twelve (12) months or next fiscal year (\$CDN):

CANADA \$ _____ U.S. \$ _____ OTHER (please list countries) _____ \$ _____
 _____ \$ _____
 _____ \$ _____
 _____ \$ _____

D) 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 (figures must equal totals in 2D 1. and 2D 2. above):						

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:						

3. PRODUCT INFORMATION

A) 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)

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

C) 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: _____

D) 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? _____

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- E) 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): _____
- F) 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): _____
- G) 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: _____
- H) 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)? \$ _____
- I) Please describe the nature of the maintenance and/or repair services. _____
- J) Does your Company subcontract these services to others? YES NO
If YES, please provide a copy of the contract for our review.
- K) Are you added to the subcontractor's policy as an additional insured? YES NO

4. RISK MANAGEMENT PRACTICES

- A) 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? _ _____
- B) 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? _____
- C) 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? _____
- D) 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? _____
- E) Does your Company follow Good Manufacturing Practices (GMP)? YES NO
Are you ISO registered? YES NO
If YES, what level? _____
- F) 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? _____
- G) 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: _____

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H) Does your Company keep laboratory animals on the premises? YES NO
If YES, please indicate the type of animals, their numbers and purpose.

ANIMAL	NUMBER	PURPOSE

I) Does your Company consult with legal counsel for issues concerning the following:

- Contractual Liability YES NO Not Applicable
- Product Labeling YES NO Not Applicable
- Product Instructions YES NO Not Applicable
- Product Guarantees YES NO Not Applicable
- Promotional Materials YES NO Not Applicable
- Instruction Manuals YES NO Not Applicable

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

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

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

Are all trial participants required to sign an informed consent form? YES NO
If NO, please explain: _____

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: _____

Who will be the principal investigators in the clinical trial(s)? _____

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: _____%

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: _____

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:

A) Please indicate the percentage (%) of products made to the specifications of others: _____ %

B) Please indicate the percentage (%) of products made to your Company's own specifications: _____ %

C) Does your Company manufacture and/or assemble the final product(s)? [] YES [] NO
If NO, please explain: _____

D) Does your Company require signed final acceptance from its customers? [] YES [] NO
If NO, please explain: _____

E) 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

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Other (please specify): _____

- F) 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

- A) 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: _____

- B) 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	OCC OR CLAIMS MADE	RETRO DATE

- C) 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

- A) Has your Company, its partners, directors, officers or employees ever had a written demand or civil proceedings for compensatory damages made against them? 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

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- 4) Amount of indemnity payment and amount of defense costs
- 5) Final dispositions or current status of claim

B) 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: _____

C) 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: _____

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 in Section 8, 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

By purchasing insurance from Creechurch International Underwriters Ltd. (Creechurch), a customer provides Creechurch 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 Creechurch's and related or affiliated companies and service providers.

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

10. WARRANTY STATEMENT

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: _____
(Authorized Representative)

DATED: _____

NAME: (Please Print) _____

TITLE/POSITION: _____