BIOMEDICAL AND LIFE SCIENCE APPLICATION
MEDICAL DEVICE LIABILITY

PLEASE ANSWER ALL QUESTIONS – IF AN ANSWER TO A QUESTION IS NONE, STATE "None" or "0"
IF THEY DO NOT APPLY, INDICATE "N/A" - IF SPACE IS INSUFFICIENT PLEASE USE SEPARATE SHEETS

GENERAL INFORMATION

1. **Named Insured** (as it should appear on the policy)**:**

_____

2. **Mailing Address:**

_____

3. **Location Address** (if different than mailing address above)**:**

_____

4. **Website Address**: _____

COMPANY INFORMATION

1. Year established: _____

2. Have you acquired any companies within the last 5 years? ☐ Yes ☐ No
   If Yes, please provide details:

3. Please list all subsidiary companies for whom cover is required. (Cover will not be provided for subsidiaries unless listed and agreed upon by us)

4. Are you a subsidiary of another company? ☐ Yes ☐ No
If Yes, please provide details:

_____

5. Have you every operated under another name? ☐ Yes ☐ No
If Yes, please provide details:

_____

6. Describe your business activities:

7. Please provide a breakdown of your gross revenue by country (DOLLAR AMOUNT):

Country		Previous 12 months	Anticipated for the next 12 months
Canada			
United States			
Other; please list:			

8. Please provide a breakdown of your business activities:

Business Activity	**% of Total Revenue**
Manufacture/sale of proprietary products	
Contract manufacture (for others)	
Wholesale distribution	
Retail	
Research (for others)	
Other; please specify _____	

9. Please list your 3 largest customers:

Customer	Size of Contract	Length of Contract	Type of Product/Service

PRODUCT INFORMATION

1. Please provide a breakdown of your Products:

Type	% of Total Revenue
Class I	
Class II	
Class III	
Class IV	
Custom made device	
Laboratory Equipment	
Other; please specify: _____	

2. a) Do any of your past or present products contain any of the following Specified Products or Specified Product Categories: ☐ Yes ☐ No

Specific products

- Infusion systems and pumps
- Mercury
- Silicone (only when used as part of an implantable medical device)
- Latex Gloves
- Metal-on-Metal implants

Specified product categories

- Birth control or Fertility Products
- Products specifically designed for pregnant women
- Unapproved goods or products
- Nanotechnology
- Surgical mesh used in urogynecology

b) If you answered Yes to question 2. a), please provide full details including dates, source, where sold and sales generated:

3. Are all of your products approved for their intended purpose by the relevant regulatory body in the territory in which they are to be distributed? ☐ Yes ☐ No
If No, please provide details:

4. Have any of your products been subject to a medical device adverse incident? ☐ Yes ☐ No
If Yes, please provide details:

5. Do you contract out product development, manufacturing, sales or distribution services? ☐ Yes ☐ No
If Yes, please provide details:

6. Are any of your products sold under other's labels or as components of other's products? ☐ Yes ☐ No
If Yes, please provide details:

7. Are any of your components imported? ☐ Yes ☐ No
If Yes, please provide details:

8. Are any of your products required to be sold sterile? ☐ Yes ☐ No
If Yes, please indicate if your company or a third party (please identify) sterilizes the product:

9. Do you provide training on the use and/or maintenance of your products? ☐ Yes ☐ No
If Yes, please provide details:

10. Do you provide maintenance and repair services? ☐ Yes ☐ No
If Yes, please provide details:

11. Do you sell your products or services via the internet? ☐ Yes ☐ No
If Yes, has the website content been reviewed by legal counsel? ☐ Yes ☐ No

12. Do you plan to introduce any new products or services within the next 12 months? ☐ Yes ☐ No
If Yes, please provide details:

REGULATORY AND COMPLIANCE INFORMATION

1. To the best of your knowledge are you currently in compliance with all applicable government regulations? ☐ Yes ☐ No
If No, please explain:

2. Have any of your products been subject to an inquiry or been investigated by any regulatory authority? ☐ Yes ☐ No
If Yes, please provide details:

3. Have any of your products been recalled, withdrawn or discontinued due to a safety or performance reason; initiated by you or a regulatory authority? ☐ Yes ☐ No
If Yes, please provide details:

4. Have all your manufacturing locations been inspected by the relevant regulatory authority? ☐ Yes ☐ No
If Yes, when was the date of the last inspection?

5. Has your manufacturing license ever been withdrawn? ☐ Yes ☐ No
If Yes, please provide details:

_____

RISK MANAGEMENT INFORMATION

1. Do you have a formal quality control program in place? ☐ Yes ☐ No
If Yes, when was it last updated?

_____

2. Do you have a formal recall plan in place? ☐ Yes ☐ No
If Yes, when was it last updated?

_____

3. Do you have a system for documenting incident reports and/or complaints? ☐ Yes ☐ No
If Yes:

a) Who is responsible for recording and handling complaints?

_____

b) How long are records retained? _____

4. Do you maintain samples of your products? ☐ Yes ☐ No
If Yes, how long are they retained? _____

5. Do you follow Good Manufacturing Practices (GMP)? ☐ Yes ☐ No

6. Are you ISO registered? ☐ Yes ☐ No

7. Are all contracts reviewed by legal counsel concerning the following:

a)	Contractual Liability	☐ Yes	☐ No	e)	Instruction Manuals	☐ Yes	☐ No
b)	Product Labeling	☐ Yes	☐ No	f)	Copyright	☐ Yes	☐ No
c)	Product Guarantees	☐ Yes	☐ No	g)	Trademark	☐ Yes	☐ No
d)	Promotional Materials	☐ Yes	☐ No	h)	Registered Design	☐ Yes	☐ No

8. For all products which you are a distributor:

a) Do you receive a certificate of products liability insurance from the manufacturer? ☐ Yes ☐ No

b) Are you added to the manufacturer's policy as an additional insured? ☐ Yes ☐ No

c) Do you retain right of recourse against the manufacturer? ☐ Yes ☐ No

9. Do you require certificates of insurance from all suppliers and sub-contractors? ☐ Yes ☐ No
If No, explain:

_____

PREMISES INFORMATION

1. Do you store any hazardous substances on your premises? ☐ Yes ☐ No
   a) If Yes, are you in compliance with all applicable laws regarding hazardous materials handling and disposal? ☐ Yes ☐ No
   b) Have you ever had a biohazard release? ☐ Yes ☐ No

2. Do you have any laboratory animals on your premises? ☐ Yes ☐ No
If Yes:
   a) Identify type of animal(s): _____
   b) Number of animals: _____
   c) Their intended purpose: _____

CLINICAL TRIAL (complete only if coverage is required)

Please attach the following for each clinical trial to be covered:

- Protocol (if final version is not available please submit Draft or Synopsis)
- Informed Consent Form

1. Do you conduct Phase 1 and/or Planned Emergency Use Trials? ☐ Yes ☐ No

2. Do you require cover for a research subject who is:
   a) Pregnant at the time of or during the course of the clinical trial or pre-trial assessment ☐ Yes ☐ No
   b) Under the age of 18 years at the time of the clinical trial or pre-trial assessment ☐ Yes ☐ No
   c) Incapable of giving their legal consent to participate in the clinical trial ☐ Yes ☐ No
   d) A prisoner ☐ Yes ☐ No
   e) An employee of yours or of the investigator ☐ Yes ☐ No

3. Please provide details of trials performed in the last 12 months:

Date Commenced	Date Completed	Protocol Number	Phase	Indication	No. of Subjects	Country

4. Please provide details of active & anticipated trials for the next 12 months

Date Commenced	Expected Completion Date	Protocol Number	Phase	Indication	No. of Subjects		Country
					Estimated	Enrolled	

5. Are all of your clinical trials approved by the appropriate regulatory authorities? ☐ Yes ☐ No

6. Are all trial subjects required to sign an informed consent form? ☐ Yes ☐ No

7. Do you require all informed consent documents be readable at a Grade 8 level or below? ☐ Yes ☐ No

8. Have you discontinued any clinical trial over concerns about the potential health risks to trial subjects? ☐ Yes ☐ No
If Yes, please provide details:

_____

9. Have any of your clinical trials been suspended or cancelled by Health Canada or equivalent local authority? ☐ Yes ☐ No
If Yes, please provide details:

_____

10. Do any of your researchers own more than 15% stock in the Company? ☐ Yes ☐ No

COVERAGE REQUIREMENTS

What type of coverage and limit of liability are you seeking?

Type of Coverage	Limit of Liability
General Liability:	
Products Liability:	
Clinical Trial Liability:	
Errors & Omissions Liability:	
Other, please specify: _____	

LOSS INFORMATION

1. Has your Company ever had a written demand or civil proceeding for damages made against them? ☐ Yes ☐ No
   If Yes, please provide the following details on a separate sheet:
   - Date of claim
   - Claimant's name
   - Nature of claim
   - Amount of indemnity payment and amount of defense costs
   - Final dispositions or current status of claim

2. Are you aware of any circumstances that might give risk to a claim? ☐ Yes ☐ No
   If Yes, please provide details:

INSURANCE HISTORY

1. Is your Company currently insured? ☐ Yes ☐ No
   If Yes, please complete the table below for the past 3 years:

Insurance Company	Policy Period	Limit of Liability	Deductible	Retroactive Date	Coverage Type	Premium

2. Has any insurance company ever:
   a) Declined you application for insurance? ☐ Yes ☐ No
   b) Refused to renew any insurance policy? ☐ Yes ☐ No
   c) Cancelled any insurance policy? ☐ Yes ☐ No

Please include the following with the application:

- Current product list
- Advertisements, brochures, descriptive literature
- Sample Service Contracts & Indemnification Agreements
- Clinical Trial Protocols and Patient Informed Consent Forms (if applicable)
- Senior staff curriculum vitae

The completion and submission of this application to the Company does not constitute a promise to provide coverage or a binder of insurance.

THE UNDERSIGNED HEREBY ACKNOWLEDGES THE TRUTH OF THE STATEMENTS CONTAINED HEREIN.

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 THAT THEY WILL IMMEDIATELY REPORT SUCH CHANGES TO THE INSURER.

THE COMPLETION AND SIGNING OF THIS APPLICATION DOES NOT CONSTITUTE A PROMISE TO PROVIDE COVERAGE. HOWEVER, IF A POLICY IS ISSUED, THIS APPLICATION SHALL SERVE AS THE BASIS OF SUCH CONTRACT AND WILL BE ATTACHED TO, AND FORM PART OF THE POLICY.

I AUTHORIZE YOU TO COLLECT, USE AND DISCLOSE PERSONAL INFORMATION AS PERMITTED BY LAW, IN CONNECTION WITH YOUR COMMERCIAL INSURANCE POLICY OR A RENEWAL, EXTENSION OR VARIATION THEREOF, FOR THE PURPOSES NECESSARY TO ASSESS THE RISK, INVESTIGATE AND SETTLE CLAIMS, AND DETECT AND PREVENT FRAUD, SUCH AS CREDIT INFORMATION, AND CLAIMS HISTORY.

For purposes of the Insurance Companies Act (Canada), this document was issued in the course of Lloyd's Underwriters' insurance business in Canada.

Signature of Applicant (authorized representative) _____ Date _____

SUBMITTED BY: _____

EMAIL: _____

For contact information visit:
www.markelinternational.ca