



## MEDICAL DEVICES INSURANCE APPLICATION

### HOW TO COMPLETE THIS FORM

Whoever fills out the form must be a principal, partner or director of the applicant firm and should make all the necessary enquiries of their fellow partners, directors and employees to enable all the questions to be answered.

If you require any extra space to complete the answers to questions contained within this application form please continue your response in the Additional Information section at the back of the form. Once you have completed the form please return directly to your insurance broker.

### SECTION 1: COMPANY DETAILS

1. Please complete the following:

Applicant company: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Mailing Address Street: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

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

2. Please state when your company was established (month/day/year): \_\_\_\_\_

3. Please briefly describe below the nature of your business activities: \_\_\_\_\_  
 \_\_\_\_\_

4. If you have any brochures or other company literature, please include it with this application.

5. Please outline below your business development plans for the next 12 months, including the number of products under development and the stage of development for each: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

*If you have a copy of an up to date business plan, please attach to this form.*

6. Please state the number of employees: Full-time: \_\_\_\_\_ Part-time: \_\_\_\_\_

7. Please provide estimates of your payroll for the next 12 months, broken down as follows:

a. Administrative and managerial: \_\_\_\_\_

b. Laboratory based staff: \_\_\_\_\_

c. Other: \_\_\_\_\_

For other, please provide full details: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

8. Do you directly work with, or store, radioactive or biohazardous materials at your premises?  Yes  No  
 If 'yes', please provide further details below, including types of materials, quantities used and how you manage the process of using, storing and disposal: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_



**SECTION 2: PREMISES DETAILS**

1. Please provide details of your premises:

a. PREMISES 1:

Street Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Details of usage (e.g. manufacturing, storage, offices etc.): \_\_\_\_\_

b. PREMISES 2:

Street Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Details of usage (e.g. manufacturing, storage, offices etc.): \_\_\_\_\_

*Please continue on a separate sheet if more than 2 premises are to be insured.*

2. Please provide details of the premises of your supply chain partners that carry out significant work on your behalf, including those where you require cover for damage to your property and those where you have a significant reliance on them for your business activities:

a. SUPPLY CHAIN PARTNER 1:

Street Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Details of Usage: \_\_\_\_\_

b. SUPPLY CHAIN PARTNER 1:

Street Address: \_\_\_\_\_

City, State, Zip: \_\_\_\_\_

Details of Usage: \_\_\_\_\_

*Please continue on a separate sheet if more than 2 premises are to be insured.*

3. Are all of the premises:

a. Constructed with external walls of brick, stone or concrete and roofed with slate, tiles, concrete, metal, asbestos or any other non-combustible material?  Yes  No

b. Free from cracks or other signs of damage that may be due to subsidence, landslip or heave and have not previously suffered damage by any of these causes?  Yes  No

c. In a good state of repair?  Yes  No

d. Self-contained with a lockable entrance door?  Yes  No

e. Protected by fire and intruder alarms that are subject to an annual maintenance contract?  Yes  No

*NOTE: We may refuse to pay a claim if all of the devices for the protection of your premises (including locks and alarms) are not put into full and effective operation whenever the premises are closed for business or left unattended.*

f. Heated by a conventional electric, gas, oil or solid fuel heating system?  Yes  No

g. Fitted with electrical installations which are inspected at least every 5 years by a qualified electrician and any defect remedied?  Yes  No

h. Lifts, boilers, steam and pressure vessels inspected and approved to comply with all of the statutory requirements?  Yes  No

**NOTE:** Assuming you have answered yes to questions g) and h) above, it is important to keep records of all relevant inspections as we may ask for evidence for these before paying a claim.



If you have answered "no" to any of the above questions, please provide further details: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

4. If any of the premises listed in 1 and 2 above contain composite or sandwich panels, please provide the following details:

- a. Full Address: \_\_\_\_\_
- b. Are panels:  Exterior  Interior
- c. Type of Panel (make, model, core material): \_\_\_\_\_
- d. Are products LPS1181: 2003 or FMRC4880 (1994) approved?  Yes  No

5. Please provide details of your contingency plans to continue your business activities, if damage at the premises listed in 2 means your supply chain partners are unable to fulfill contractual commitments:

- a. Supplier Name: \_\_\_\_\_
- b. Nature of Reliance: \_\_\_\_\_
- c. Contingency Plans: \_\_\_\_\_  
\_\_\_\_\_

6. Is your stock sensitive to changes in environmental conditions?  Yes  No  
If yes, please answer the following:

- a. What proportion of stock is temperature sensitive? \_\_\_\_\_
- b. Is all stock stored in fridges / freezers which are less than 3 years old, or subject to maintenance agreements?  Yes  No
- c. Is all electrical equipment/switch gear protected by anti-power surge devices?  Yes  No
- d. Are all fridges/freezers connected to automatic self-starting power generators?  Yes  No  
If yes, how many hours back up is provided? \_\_\_\_\_
- e. Do you have an alarm system that activates if the temperature falls outside the prescribed range?  Yes  No
- f. Is the alarm system monitored by a third party central station  Yes  No
- g. Is stock duplicated in more than one freezer on the same site?  Yes  No
- h. Is stock duplicated in more than one freezer at different sites?  Yes  No
- i. Do you have a formal Business Continuity Plan for a power outage or failure in storage arrangements?  Yes  No
- j. Are specialist couriers used if stock is moved?  Yes  No

7. Is cover for stock in transit required?  Yes  No  
If yes, please state the stock consignment values:

	Annual Value	Max Value of One Consignment
Domestic	\$	\$
Outside (domestic) country, but within the continent	\$	\$
Elsewhere in the world	\$	\$



8. Will you transport stock to areas where the government currently advises against travel?  Yes  No
If yes, please provide details: \_\_\_\_\_

SECTION 3: ACTIVITIES

1. Please state your revenue received in respect of the following years:

Table with 4 columns: Last Complete Financial Year, Estimate for Current Financial Year, Estimate for Next Financial Year, and rows for Domestic Revenue, Other Territory Revenue, Total Revenue, Gross Profit.

Date of financial year end (MM/DD/YY): \_\_\_\_\_ Currency: \_\_\_\_\_

2. Please state the percentage of your fees received in respect of each device classification:

Table with 4 columns: Class I, Class IIa, Class IIb, Class III, each with a percentage field.

3. Please state the percentage of your fees received in respect of each of the following:

Table with 2 columns: Description (Sale of own product, Manufacture and distribution, Contract manufacture, Distribution of third party product, Other) and Percentage.

4. Please state the percentage of your revenue received in respect of each of the following:

Pediatric: \_\_\_\_\_%
Clinical: \_\_\_\_\_%
Ambulatory: \_\_\_\_\_%
Home Use: \_\_\_\_\_%
Products with Cosmetic Applications: \_\_\_\_\_%
Other: \_\_\_\_\_%

5. Please state the percentage of your fees received in respect of each of the following:

Table with 2 columns: Category (Active implantable, Anesthesia, Analytical instruments, Cardiovascular, Dental, Diagnostic kits, Durable equipment, Hospital consumables, Lasers, Monitoring equipment, Passive implantable, Rehabilitation) and Percentage.



Dialysis:	%
Drug delivery:	%

Respiratory:	%
Surgical:	%

**SECTION 4: HEALTH & SAFETY MANAGEMENT**

1. Do you use a full-time risk manager?  Yes  No  
If no, how do you control and prioritize risk? \_\_\_\_\_
2. Do you have, in place, a Medical Device Vigilance System, Safety Surveillance System or similar?  Yes  No  
If yes, please provide names and status of people responsible: \_\_\_\_\_  
If no, please explain your method for safety oversight and reporting: \_\_\_\_\_
3. Have you ever had an inspection visit by a regulatory body?  Yes  No  
If yes:
  - a. When was the last visit? (MM/DD/YY) \_\_\_\_\_
  - b. What requirements or recommendations were made and do any remain outstanding? \_\_\_\_\_
4. Have you ever been subject to a written warning, enforcement notice or prosecution by a regulatory body (e.g. MHRA)?  Yes  No  
If yes, please provide details: \_\_\_\_\_
5. Have you ever been subject to a Medical Device Alert (MDA), Safety Alert Broadcast (SAB), Hazard Alert, Medical Device Report (MDR) or similar?  Yes  No  
If yes, please provide details: \_\_\_\_\_
6. Have you ever withdrawn or recalled a product or discontinued product sales for safety reasons?  Yes  No  
If yes, please provide details: \_\_\_\_\_
7. Have you been associated with a serious adverse event that was ultimately shown to be device related?  Yes  No  
If yes, please provide details: \_\_\_\_\_
8. How do you monitor off-label use (use of a product contrary to your own conformity assessment and certification) of your products by customers and medical professionals?

**SECTION 5: CONTRACT MANAGEMENT**

1. Are all rights of recourse retained against all supply chain partners?  Yes  No  
If no, please explain why: \_\_\_\_\_



- 2. Will supply chain partners carry the following insurance:
  - a. Products liability for contract manufacturers?  Yes  No
  - b. Professional liability for service providers and other consultants?  Yes  No
- 3. In your written contracts do you ever accept liability for consequential loss or financial damages?  Yes  No  
 If yes, please provide details: \_\_\_\_\_
- 4. Do your written contracts ever contain "Hold Harmless" or "Indemnification" clauses in which you accept liability for loss of life, injury, property damage, or financial losses in circumstances other than where they are caused by your negligence?  Yes  No  
 If no, please explain: \_\_\_\_\_

**SECTION 6: COVER LIMITS AND SUMS INSURED**

- 1. Would you like cover for damage to your property?  Yes  No  
 If no, please go to question 7.  
*If yes, please attach information regarding the value of the following property, including estimated maximum values at risk at any one time where applicable, at the premises listed in question 2.1 and 2.2:*
  - a. Buildings
  - b. Tenants improvements, fixtures & fittings
  - c) Machinery and laboratory equipment
  - c. Fixed electronic equipment
  - d. Portable electronic equipment
  - e. Own stock
  - f. Third party stock in your custody and control
  - g. Any other property not listed above
- 2. Would you like the policy to cover any of the following:
  - a. Spoilage of perishable stock?  Yes  No
  - b. Pollution or contamination?  Yes  No
  - c. Machinery breakdown?  Yes  No
  - d. Property in transit?  Yes  No
  - e. Terrorism?  Yes  No
  - f. Ideologically motivated attack (that is not declared an act of terrorism by the government)?  Yes  No
- 3. Would you like business interruption cover?  Yes  No  
 If yes, please state the First Loss sum insured required: \_\_\_\_\_
- 4. Please state the sublimits required for business interruption following damage at the premises of your supply chain partners listed in question 2.2:

Supply Chain Partner Name	Business Interruption Sublimit

- 5. Please state the indemnity period required (6 - 24 months): \_\_\_\_\_



- 6. Would you like cover for Third Party Liability?  Yes  No  
If yes, please state the limit of liability required: \_\_\_\_\_
- 7. Would you like cover for products liability?  Yes  No  
If yes, please state the limit of liability required: \_\_\_\_\_
- 8. Would you like cover for Errors and Omissions?  Yes  No
- 9. Would you like cover for Clinical Trials?  Yes  No  
If yes, please complete our Clinical Trials application.
- 10. Would you like cover for D&O?  Yes  No  
If yes, please complete our D&O application.

**SECTION 7: CLAIMS EXPERIENCE & INSURANCE HISTORY**

1. Please provide details of your current insurance:

Type	Expiration Date	Retroactive Date	Insurer
Property and Business Interruption		N/A	
Third Party Liability		N/A	
Products Liability			
Errors & Omissions			
Clinical Trials			
Directors & Officers Liability			

2. Regarding all of the types of insurance to which this application form relates, AFTER INQUIRY:

- a. Are you aware of any loss or damage, whether insured or not, that has occurred to any of the Companies to be insured (or to any existing or previous business of the partners or directors of any of the Companies to be insured) within the last 5 (five) years, or
- b. Are you aware of any circumstances which may give rise to a claim against any of the Companies to be insured or any partners or directors thereof, or
- c. Have any claims or cease and desist orders been made against any of the Companies to be insured, or partners or directors thereof, or
- d. Have any partners or directors of the Companies to be insured been found guilty of any criminal, dishonest or fraudulent activity or been investigated by any regulatory body?

With reference to questions a, b, c and d above:  Yes  No

*If the answer to the above is yes, then please attach full details including an explanation of the background of events, the maximum amount involved or claimed, the status of the claim or circumstance and any reserve or payment made by you or by Insurers, and the dates of all developments and payments.*

- I declare that after proper inquiry the statements and particulars given above are true and that I have not mis-stated or suppressed any material fact.
- I agree that this Application Form, together with any other material information supplied by me shall form the basis of any contract of insurance effected thereon.

